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UNIVERSITY OF ALBERTA

FACTORS IN THE DEVELOPMENT OF EXIT-SITE INFECTIONS ASSOCIATED WITH PERITONEAL DIALYSIS CATHETERS

BY

CORNELIA ANN (LEANNE) DEKKER ©

A thesis submitted to
the Faculty of Graduate Studies and Research
in partial fulfillment of the requirements for
the degree of Master of Nursing

FACULTY OF NURSING

EDMONTON, ALBERTA

FALL 1991

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DEGREE: Master of Nursing

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The undersigned certify that they have read, and recommend to the the Faculty of Graduate Studies and Research for acceptance, a thesis entitled "FACTORS IN THE DEVELOPMENT OF EXIT-SITE INFECTIONS ASSOCIATED WITH PERITONEAL DIALYSIS CATHETERS" submitted by CORNELIA A. (LEANNE) DEKKER in partial fulfillment of the requirements for the degree of MASTER OF NURSING.

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August 29, 1991

DEDICATION

To my nursing colleague, Deanna Van Eldik whose exemplary practice of nursing instilled in me a love for, and a commitment to, the profession of nursing.

Abstract

The purpose of this study was to investigate the possible relationship between the initial post-operative nursing care of the person with a peritoneal dialysis catheter and the later development of exit-site infections. Specifically, the research study addressed whether the frequency of sterile dressing changes, duration of time post-operatively that the catheter is covered with a sterile dressing and the type of personnel (nurses, patients, and/or family members) performing the dressing change influenced the later development of exit-site infections.

The sample (n=130) was comprised of all adult patients who had a peritoneal dialysis catheter inserted at one hospital facility between January 1985 and January 1990. Information regarding the development of exit-site infections and the post-operative nursing care was collected retrospectively, utilizing a data collection instrument developed by the investigator. Prior to its use, face and content validity of the instrument were established by an expert panel.

The incidence of exit-site infection within the sample was 33.8% at six months, and exit-site infections developed in nearly half (44.8%) of the

sample by one year following catheter insertion. Odds ratio, chi-square and logistic regression analyses suggested that the presence of a suture at the exit-site decreased the incidence of exit-site infections during the initial year following catheter insertion. The frequency of sterile dressings performed on the catheter during the first post-operative week and the length of time following catheter insertion that the patient and/or family member commenced the performance of sterile dressings were associated with the development of exit-site infections within six months of catheter insertion through the use of chi-square analysis. However, this association was not maintained when these variables were subjected to analysis by logistic regression.

The findings of this study suggest implications for the post-operative nursing care of the person with a peritoneal dialysis catheter. Further research is necessary to understand the possible role that the initial post-operative nursing care of the person with a peritoneal dialysis catheter may have in the prevention of exit-site infections.

ACKNOWLEDGEMENT

I gratefully acknowledge the support and assistance of my thesis committee and others, in the completion of this project. The thesis committee, consisting of Drs. Anita Molzahn, Marilynn Wood and Sharon Warren provided ongoing support and encouragement throughout the endeavour. In particular, the patience and guidance of Dr. Molzahn, my thesis supervisor was invaluable.

The members of the expert panel, Stephanie Fox, Donna Mallach, Cindy Alton, and Dr. Mrinal Dasgupta contributed their expertise in the care of the patient with a peritoneal dialysis catheter towards my work. The home dialysis nursing staff and the staff of the medical records department in the institution where the research was conducted are acknowledged for their assistance in facilitating data collection.

Lastly, the financial support of the Alberta Foundation for Nursing Research (student research bursary), the American Nephrology Nurses' Association (Amgen research grant), and the Kidney Foundation of Canada (scholarship) is gratefully acknowledged. It should be noted that the views and findings of the study are those of the author, and endorsement of these findings by these organizations should not be inferred.

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I. INTRODUCTION

The person with end-stage renal disease requires ongoing medical intervention, dialysis therapy or kidney transplantation to sustain life. In some circumstances, dialysis therapy is used as an adjunct treatment to transplantation. However, for many people dialysis is the sole option for continuing life.

There are two forms of dialysis therapy, hemodialysis and peritoneal dialysis. Hemodialysis involves passing the person's blood through an artificial kidney, where, by diffusion and ultrafiltration, the waste products of metabolism, normally excreted by the kidney, are removed. Three to six hour hemodialysis treatments are required two to three times weekly to attain adequate dialysis. Major complications of the treatment include a reliance upon a vascular access to obtain the large volume of circulating blood required, and hypotension resulting from fluid volume shifts. These complicating factors limit the success of hemodialysis in a person with compromised cardiovascular function.

In contrast, peritoneal dialysis is not dependent upon access to the person's blood stream. Rather, a sterile electrolyte solution is instilled into the person's peritoneal cavity through an implanted catheter. During the dwell phase (while the fluid is within the peritoneal cavity), excess fluid and metabolic waste products are removed through the processes of osmosis and diffusion. The solution is then drained from the peritoneal cavity.

Peritoneal dialysis was introduced and began to be used for patients in acute renal failure during the 1950's. However, it was not until the 1960's and the introduction of a silastic catheter for continual access into the peritoneal cavity, that chronic intermittent peritoneal dialysis was feasible for the person with end-stage renal disease (Gutch, 1964; Palmer, Quinton, & Gray, 1964; Tenckhoff & Schechter, 1968). Chronic intermittent peritoneal dialysis is time and labour intensive, requiring a treatment length of 18 to 24 hours, two or three times weekly to attain adequate dialysis. Therefore, prior to the development of Continuous Ambulatory Peritoneal Dialysis (CAPD), peritoneal dialysis was primarily used on a temporary basis. Peritoneal dialysis was used for patients who required revisions of their blood access, or in situations where anticoagulation posed significant risks to patients (e.g., after major surgery).

CAPD involves the exchange of the sterile electrolyte solution, four times daily, thus facilitating an ongoing cleansing of the blood of waste products and excess fluid normally excreted by healthy kidneys. The introduction of this form of peritoneal dialysis was made feasible by the availability of peritoneal dialysis solution in sterile plastic bags, beginning in the 1970's. These bags made it possible to leave the catheter attached to the tubing, and to use the empty bag for drainage at the time of the next exchange.

The CAPD procedures, although dependent upon sterile technique, are simple, and as such, allow the person to perform dialysis independently, or with a family member's assistance at home. The simplicity of CAPD, and the use of the person's peritoneal membrane for fluid removal and diffusion without involving the vascular system, has facilitated an expansion of dialysis therapy.

Statement of the Problem

Peritoneal dialysis has become an accepted form of renal replacement therapy for the person with end-stage renal disease. For children and the elderly, or for the person with diabetes mellitus or atherosclerotic heart disease in addition to renal failure, CAPD is the dialysis procedure of choice (Drukker, 1988; Hamburger et al., 1990; Zappacosta & Perras, 1984). Complications of the treatment which lead to transfer to hemodialysis are primarily loss of membrane permeability and infection (Zappacosta & Perras, 1984). The major infectious complication of CAPD is peritonitis; however, exit-site infections hold significant morbidity, leading to tunnel infection, peritonitis, and catheter removal (Abraham et al., 1988; Copely, 1987; Holley, Foulks, Moss, & Willard, 1989; Pegues, Arduino, Bland, & Jarvis, 1989; Piraino, Bernardini, & Sorkin, 1986; 1989b; Twardowski & Prowant, 1986).

Exit-site infections develop in 22 to 46% of the patients on CAPD within the first year following insertion of the peritoneal catheter (Abraham et al., 1988; Lindbald, Novak, & Nolph, 1989; Luzar & Lewis, 1989), with an average of 10% of these infections occurring during the initial post-operative period (Copely, 1987). Attempts to treat exit-site infections without catheter removal have had limited success, and infections that are associated with a tunnel infection or peritonitis require removal of the catheter for eradication of the infectious process (Khanna & Twardowski, 1988; Nicols & Nolph, 1983; Piraino, Bernardini, & Sorkin, 1987; Vas, 1981a). Catheter removal necessitates hospitalization and temporary or permanent transfer to hemodialysis, causing inconvenience and anxiety for the person (Piraino et al., 1986; Prowant, 1984). Furthermore, it has been suggested that exit-site infections occurring early in the person's CAPD experience discourage the person from continuing with CAPD (Piraino et al., 1989b).

Copely (1987) reviewed the suggested methods for preventing exit-site infections, and called exit-site infections the "Achilles heel" of CAPD, since advances in CAPD techniques and devices have reduced the incidence of peritonitis. In the prevention of exit-site infections, a number of protocols for the care of the healed catheter exit-site have been developed (Clayton, Quinton, & Oreopoulos, 1981; Fuchs, Gallagher, Jackson-Bey, Krawtz, & Schreiber, 1990; Jensen, Davidson, Pomeroy, Cox, & McMurray, 1989; Moore, 1989; Prowant et al., 1988; Starzomski, 1984; Travenol Laboratories Inc., 1979; Waraday et al., 1987). Furthermore, it has been suggested that catheter structure (Ash, Slingenereyer, & Schardin, 1983; Diaz-Buxo & Geissinger, 1984; Khanna & Oreopoulos, 1983; Kim et al., 1984; Lindbald, Hamilton, Nolph & Novak, 1988; Smith, 1984; Twardowski & Prowant, 1986) and catheter insertion techniques (Abraham et al., 1988; Allon, Soucie, & Macon, 1988; Perras, Zappacosta, & Mattern, 1985; Piraino, Bernardini, Johnston, & Sorkin, 1989; Stone et al., 1986; Vogt et al., 1987) influence the development of exit-site infections. However, one area of peritoneal dialysis catheter care, the care of the catheter in the initial post-operative period, has been largely ignored. Therefore the question arises, does the initial post-operative care of the person with a peritoneal dialysis catheter have an influence on the later development of exit-site infections?

Purpose of the Study

The purpose of this study was to examine the effect of the initial post-operative nursing care of the person with a peritoneal dialysis catheter on the later development of exit-site infections (within two specified time periods, from catheter insertion until six months, and from six months to one year post catheter insertion).

Specific research questions that arose from this purpose were:

Do the duration and frequency of sterile dressing changes have an effect on the later development of peritoneal dialysis catheter exit-site infections?

Is there a difference in the incidence of exit-site infections when nurses, as opposed to patients and/or family members perform the sterile dressing changes on the peritoneal catheter in the initial post-operative period?

Do patient characteristics (e.g., age, gender, visual impairment, and/or co-morbid conditions), catheter insertion factors (e.g., catheter type, location of exit-site, direction of catheter tunnel, use of prophylactic antibiotics, and/or use of a suture at the exit-site), type of germicidal solution used in sterile dressing changes, methods of healed exit-site care used, and/or length of time from catheter insertion until peritoneal dialysis commenced have an effect on the development of exit-site infections in this CAPD program?

Definition of Terms

__Exit-site Infection__: A peritoneal dialysis catheter exit-site infection exists when there is: 1. a record on the patient's medical record of erythema (redness) at the exit-site (with or without exudate), and 2. a concurrent prescription for antibiotic therapy. An exit-site infection may exist without a positive culture.

__Healed Exit-site Care__: The daily cleansing of the healed exit-site in the shower or bath, using a surgical scrub solution. Dressings may be worn over the healed exit-site at the patient's discretion and the use of tape to stabilize the catheter is suggested.

__Initial Post-operative Period__: The initial post-operative period is the period of time following catheter insertion until the person commences a healed exit-site care regimen. For the purposes of analysis, this period is designated to be seven weeks in length.

__Peritoneal Dialysis__: The use of the peritoneal membrane to facilitate the transfer of metabolic waste products and excess fluid, by diffusion and osmosis, from the blood stream into a sterile electrolyte solution contained within the peritoneal cavity. This solution is exchanged through a peritoneal dialysis catheter on a regular basis (usually four times daily). The volume and frequency of the solution exchange is determined by the physician and is dependent upon the individualized dialysis requirements of the person.

Peritoneal Dialysis Catheter: A silastic catheter permanently implanted through the abdominal wall into the peritoneal cavity through which dialysate solution is transferred into and out of the peritoneal cavity.

Sterile Dressing Change Procedure: The use of the principles of sterile technique to perform a dressing change on the peritoneal catheter's exit-site. These procedures include the use of a mask and sterile gloves by the person performing the dressing change, and the use of sterile supplies for the dressing materials.

II. LITERATURE REVIEW

The purpose of this chapter is to review the literature related to definitions of exit-site infection and the factors associated with the development of these infections. Following the discussion of the differing definitions found within the literature of what constitutes an exit-site infection, the healing process of the exit-site wound is described. Then factors identified as influencing the development of exit-site infections will be outlined. These factors include characteristics specific to the patients, catheter insertion factors, and methods used for the care of the healed exit-site. The care of the person with a peritoneal dialysis catheter during the initial post-operative period concludes the literature review.

Definition of an Exit-site Infection

Within the literature there are conflicting definitions of what constitutes an exit-site infection. Although most clinicians agree that redness at the exit-site is indicative of the development of an infectious process (Abraham et al., 1988; Cantaluppi et al., 1985; Holley, Bernardini, Johnston, & Piraino, 1990; Khanna & Twardowski, 1988; Luzar et al., 1990; Pegues et al., 1989; Piraino, 1989; Waraday et al., 1987), the other criteria to be met before diagnosis of an exit-site infection is made are not definitive. The presence of exudate, considered by some to be a sign of impending infection (Copely, 1987; Copely, Smith, Koger, Rodgers & Fowler, 1988; Pegues et al., 1989; Prowant et al., 1987), has also been described as normal drainage from the catheter's sinus tract (Pierratos, 1984). Many clinicians suggest that infection should not be diagnosed and treatment commenced until the drainage is purulent in nature (Ferguson & Tzamaloukas, 1988; Fuchs et al., 1990; Khanna & Twardowski, 1988; Ogden, Benavente, Wheeler, & Zukoski, 1986; Oreopoulos et al., 1987; Scalamogna, Castelnova, De Vecchi, Guerra, & Ponticelli, 1988). In addition, the value placed on a positive culture of the exudate is conflicting. Some authors specify that positive cultures are an essential component of diagnosis (Davis, Ogg, Cameron, Poston, & Noble, 1989; Ferguson & Tzamaloukas, 1988; Keane et al., 1989; Moore, 1989; Ogden et al., 1986), while others suggest that cultures of exit-sites are misleading (Levy, Balfe, Geary, Fryer-Keene, & Bannatyne, 1990), and have limited value, serving only to increase the cost of treatment (Piraino, Bernardini, & Johnston, 1990). Frequently, multifactorial criteria are used in the definition of what constitutes an exit-site infection, with the criteria of redness at the exit-site used in conjunction with one or all of the following: pain, drainage, induration, and/or hardness at the exit-site (Bartelt et al., 1986; Fuchs & Schreiber, 1985; Starzomski, 1984). Recently, it has been suggested that the use of a non-invasive scanning technique, ultrasound, is of value in the diagnosis of exit-site infection (Holley et al., 1989).

In an attempt to clarify and standardize the definition of exit-site infection, researchers have put forth suggestions for grading systems to be used in the surveillance of peritoneal dialysis catheter exit-sites (Holley, Boyrer, & Moss, 1988; Schönborg & Ahlmén, 1991; Twardowski, 1990). One such grading system employs the use of four classes of healed exit-sites: healthy, infected, equivocal, and traumatized. Healthy exit-sites are further differentiated into perfect and good, dependent upon the extent of epidermis visible in the sinus tract. This classification relies on the use of magnification and repeated photographs of the exit-site and sinus tract to visually identify changes in the character of the exit-site. In addition, aspirations of washings of the sinus tract are necessary for cellular identification (Twardowski, 1990). Although promising, Twardowski's classification is limited by the costs of photography, and the need for repeated analyses of the aspirations. Further revision and standardization of classification schemes regarding the character of catheter exit-sites are necessary prior to the development of a standardized definition of what constitutes an exit-site infection.

Healing of the Catheter-Skin Junction

Following the implantation of the catheter into the abdominal wall, stratified squamous epithelial cells grow down from the exit site to the subcutaneous catheter cuff creating a sinus tract. The subcutaneous cuff acts to stabilize the catheter and works as a barrier, preventing bacteria from entering the catheter's tunnel into the peritoneal cavity (Copely, 1987; Khanna, 1982). It has been suggested that a skin reaction to the silastic catheter occurs during the healing process. This reaction includes the formation of granulomata, fibrosis, and cellular infiltration at the exit-site (Amair, deCamejo, Dominguez, Boissiere, 1986; Ash, 1984). The role that this reaction may play in the development of exit-site infections is unclear.

Identification of bacteria encased in biofilm on the extra- and intra-luminal surfaces of infected and non-infected catheters (Dasgupta et al., 1986), supports the hypothesis that the subcutaneous cuff plays a role in preventing peritonitis from contamination of the exit-site. Biofilm, also termed "slime", is produced as a result of bacterial colonization of the catheter. Coagulase negative staphylococci, normally present on the skin surface, readily attach to foreign objects implanted into the body. Following colonization, the bacteria produce a large quantity of this extracellular material that covers the implanted device, preventing clearance of the bacteria by the body's host defense mechanisms (Goldman, 1990).

Staphylococcus aureus and Staphylococcus epidermidis are the causative agents in 40 - 60% of all exit-site infections (Davis et al., 1989; Holley et al., 1990; Luzar et al., 1989; Piraino, Bernardini, Peitzman, & Sorkin, 1987; Scalamogna et al., 1988;

Zimmerman, O'Brien, Wiedenhoeft, & Johnson, 1988). In an attempt to decrease the risk of exit-site infection, increasing attention has been given to surveillance and treatment of patients and/or family members who are carriers of Staphylococcus aureus. Reports confirm that patients undergoing peritoneal dialysis have a higher than normal incidence of positive nasal cultures with Staphylococcus aureus (Ahrens et al., 1987; Davis et al., 1989; Luzar et al., 1989; Pignatari et al., 1990; Sesso et al., 1989; Sewell, Clarridge, Lacke, Weinman, & Young, 1982; Zimmerman et al., 1988), and suggestions for ongoing treatment of CAPD patients who are Staphylococcus aureus carriers with rifampin, are appearing in the literature (Dryden, Ludlam, Wing, & Phillips, 1991; Morton, Walswe, & Holmes, 1987; Piraino, 1990; Zimmerman & Johnson, 1989). In addition, the use of long-term antibiotic prophylaxis has been suggested to decrease the early post-operative bacterial colonization of peritoneal catheters (Starmann & Bauer, 1989).

Healing of the exit-site wound occurs through secondary intention, since the presence of the catheter prevents skin edges from closing. Healing occurs slowly with granulation tissue composed of collagen and proteoglycans filling the cavity created by the catheter. This granulation of the wound continues until the base is almost level with the surrounding skin, and it is at this point that epithelium begins to grow over the surface restoring the integrity of the skin (Clark, 1988; Thomas, 1990). The tunnels of peritoneal catheters have been examined upon removal of the catheter, and from these examinations, it has been suggested that the healing process of catheter tunnels is lengthy (Twardowski et al., 1991).

Patient Characteristics

Characteristics of patients undergoing peritoneal dialysis, such as advanced age and the presence of insulin dependent diabetes, have been studied in relation to the development of exit-site infections. Elderly patients do not have a higher incidence of exit-site infections when compared to younger patients (Ataman et al., 1988; Nicholson, Donnelly, Burton, Veitch, & Walls, 1990). However, patients with insulin dependent diabetes have been shown to have an increased incidence of exit-site infections compared to non-diabetics (Bernardini, Piraino, Centa, Johnston, & Sorkin, 1988), and diabetic women are more at risk for the development of catheter tunnel infections than are diabetic men (Bernardini, Holley, & Piraino, 1991). In addition, it has been suggested that patients who were not able to visually examine their exit-site, had a higher incidence of exit-site infections than did those patients for whom the exit-site was easily visible (Suzuki et al., 1989).

Catheter Insertion Factors

Current catheters used for peritoneal dialysis are based upon the design of a silastic catheter developed in the early 1960's (Tenckhoff & Schechter, 1968). Although variations have been considered, the Tenckhoff catheter remains the catheter of choice (Ash, 1986; Copely, 1987; Khanna & Twardowski, 1989). Khanna and Oreopoulos (1986) suggest that the ideal access for peritoneal dialysis would be a catheter that is biocompatable, safe, durable, and painless to insert. Modifications in the design of the catheter have been made, and research into the effect that these modifications have on the development of exit-site infections has been conducted (Ash et al., 1983; Diaz-Buxo & Geissinger, 1984; Khanna & Oreopoulos, 1983; Kim et al., 1984; Ogden et al., 1986; Smith, 1984;

Twardowski et al., 1985; Twardowski, Prowant, Khanna, Nichols, & Nolph, 1990). However, due to the lack of long term experience with these catheters, the results are inconclusive (Copely, 1987).

The association between the number and positioning of the catheter cuffs, and the development of exit-site infections has been considered. For example, although double cuffed catheters have a risk of cuff extrusion and erosion (Copely, 1987; Khanna & Twardowski, 1988), the incidence of exit-site infections in patients with a double cuffed catheter was found to be increased (Hamilton & Ingriam, 1986), similar (Kim et al.,1984), or decreased (Diaz-Buxo & Geissinger, 1984; Lindbald et al., 1989; Smith, 1984; Twardowski et al., 1985), to the incidence of exit-site infections in patients with a single cuffed catheter. These conflicting results may be a result of the position of the cuff. Single catheter cuffs may be placed subcutaneously or in the deep facia beneath the rectus muscle.

In addition to the structural features of the catheter, a number of surgical techniques have been studied in relation to the incidence of exit-site infections. The location of the exit-site on the abdomen (Piraino et al., 1986), the direction of the subcutaneous tunnel (Cruz et al., 1987; Khanna & Twardowski, 1988; Tenckhoff & Schechter, 1968), and the percutaneous or incisional insertion of the catheter (Allon et al., 1988; Nicholson et al., 1990; Perras et al., 1985; Waraday et al., 1987) have been implicated in the development of exit-site infections.

Current recommendations for catheter insertion and placement include tunnelling the catheter downward towards the exit-site and avoiding the belt-line as a location for the exit-site (Copely, 1987). Furthermore, it has been suggested that the placement of the external subcutaneous cuff a distance of two or three centimetres from the exit-site and creation of a subcutaneous tunnel of at least eight centimetres will prevent cuff extrusion, and promote catheter stability (Copely, 1987; Khanna & Twardowski, 1988; Vogt et al., 1987).

The use of prophylactic antibiotics at the time of catheter insertion has been suggested (Copely, 1987; Khanna & Twardowski, 1988; Oreopoulous et al., 1987; Piraino, 1989). In addition, a report on the incidence of exit-site infections within an selected sample suggested that the use of prophylactic antibiotics contributed towards a lower incidence of post-operative catheter infections (Copely et al., 1988). However, in other studies no difference has been found in the incidence of exit-site infections and/or peritonitis with or without the use of prophylactic antibiotics has been found (Dimitriadis, Vagropoulos, Paschalidou, Antoniou, & Malaka, 1987; Nolen, Johnson, O'Brien, Engeseth, & Zimmerman, 1988). Randomized clinical trials of the effect of prophylactic antibiotics at the time of catheter insertion on the incidence of exit-site infections are not available.

Emphasis has been placed upon the best method for creating an exit-site for the catheter. It has been suggested that a snug exit-site, created by a stab wound, and without the use of suture material at the exit-site will decrease exit-site infections (Oreopoulous et al., 1987). In a small series (n = 24), it was reported that although the incidence of exit-site infections was similar in patients with and without sutures at the exit-site, the presence of a suture complicated the treatment of early post-operative exit-site infections. The 12 exit-site infections in those patients without a suture at the exit-site were treated successfully with antibiotics. In contrast, those eight patients with a suture at the exit-site required catheter removal to eradicate the infectious process (Tiedke, Kanas, & Westen, 1991).

Healed Exit-site Care

Copely (1987) cautions that tension and stress on the catheter will disturb the barrier created by the growth of collagen fibres into the subcutaneous catheter cuff. Therefore, the focus of catheter care is on cleaning the catheter - epithelial junction and preventing trauma to the exit-site.

Research on the care of the peritoneal dialysis exit-site indicates that the best method for daily cleaning of a healed exit-site is washing the exit-site with soap and water. Use of a dry gauze dressing is optional (Oreopoulos et al., 1987; Prowant et al., 1988; Travenol Laboratories Inc, 1979; Waraday et al., 1987). Painting of the skin surrounding the exit-site with povidone-iodine has been suggested (Travenol Laboratories Inc., 1979). However, conflicting reports regarding the value of using povidone-iodine can be found (Fuchs et al., 1990; Luzar et al., 1990; Prowant et al., 1988). The use of povidone-iodine has been questioned because povidone-iodine may cause trauma to the exit-site because of a cytotoxic effect on wounds

(Rodeheaver et al., 1982). It has also been implicated in an outbreak of pseudomonas exit-site infections in at least one centre (Goetz & Muder, 1989).

The use of a dressing on a healed exit-site is common. However, exit-site infections do not seem to be influenced by the use of, or type of dressing (Clayton et al., 1981; Starzomski, 1984). Starzomski (1984), citing Lawrence (1982), suggested that people may prefer to wear dressings over peritoneal catheters since the dressing decreases the visibility of the wound and may affect the patient's perception of the social acceptability of the catheter. In agreement, Moore (1989) noted that a group of patients using a polyurethane dressing over the exit-site preferred it to the standard gauze dressing because the polyurethane dressing decreased the visibility of the catheter beneath the person's clothing, and did not require removal for showering. Occlusive dressings have been shown to be beneficial in young children (Watson, Vigneux, Hardy, & Balfe, 1985), and have been suggested for Staphylococci nasal carriers (Piraino, 1990).

In addition to recommendations regarding the daily cleaning of the catheter, it has been suggested that stabilization of the catheter on the abdominal wall decreases exit-site infections. In children on CAPD, there is an increased incidence of exit-site infections in children who continually play with their catheter, as compared to those children who ignore the catheter (Stone et al., 1986; Watson et al., 1985). Furthermore, the results of a small comparative study (n = 19) suggested that wearing tight clothes irritated the exit-site and increased the incidence of exit-site infection (Ferguson & Tzamaloukas, 1988). These results suggest that excessive movement and stress at the exit-site contributes to the development of exit-site infections by disturbing the barrier created by the subcutaneous catheter cuff.

Recently, the use of CAPD with a disconnect system (a system whereby the catheter is disconnected from the tubing and/or the empty dialysate bag with each exchange), and/or Continuous Cyclic Peritoneal Dialysis (the use of a machine to perform the dialysis exchanges during the night while the person is sleeping), have been found to decrease the incidence of exit-site and tunnel infections (Burkart, 1988; Holley, Bernardini, & Piraino, 1990; Piraino et al., 1989a, 1990; Vogt et al., 1987). These results support the possible role that tension and stress at the catheter-skin junction may have on the development of exit-site infections. However, a multicentre randomized clinical trial comparing the use of the Y-set (a disconnect system) with standard CAPD, found no differences in the incidence of exit-site infections between the two systems (Churchill et al., 1989).

Initial Post-operative Nursing Care

In the initial post-operative period, recommendations for catheter care involve the use of sterile dressings (Copely, 1987; Copely et al., 1988; Fuchs et al., 1990; Khanna & Twardowski, 1989; Levy et al., 1990), and limiting the performance of the dressing procedure to the dialysis nursing staff and/or physicians (Clayton, 1981; Copely, 1987; Copely et al., 1988; Fuchs et al., 1990; Khanna & Twardowski, 1989; Piraino, 1989). Suggested care of the peritoneal catheter during the initial post-operative period includes leaving the initial post-operative dressing in place for a period of not less than seven days, and the use of tape to stabilize the catheter, thus avoiding torque movements of the catheter at the exit-site (Khanna & Twardowski, 1988; Oreopoulous et al., 1987). Furthermore, Khanna and Twardowski (1988) suggest that the sterile dressings be changed on a weekly basis, and that a sterile dressing procedure be continued for a minimum of six weeks to ensure adequate healing at the catheter-skin junction. In contrast, Copely (1987) suggests that the sterile dressing be changed on a daily basis and worn only until the catheter-skin interface appears to be healed. In a later report on post-operative catheter-related infections, Copely and colleagues (1988), suggested that in diabetics and immunosuppressed patients, the daily dressing change is imperative. In other patients, without these additional medical problems, the daily dressing can be missed on occasion if adequate healing appears to be occurring. No criteria were given for assessment of adequate exit-site healing.

Research regarding the frequency of the initial post-operative dressing changes on peritoneal catheters is limited. One group of researchers (Jensen et al., 1989) included frequency of sterile dressing changes as a component in their cohort study of catheter care protocols. However, each catheter care protocol studied included a number of modifications that may have influenced the development of exit-site infections. Therefore, the decreased incidence of exit-site infections can not be attributed to the modification in dressing change frequency. Another group recently described a population with a 40% incidence of exit-site infections within 14 days of catheter insertion. This high incidence of infections was attributed to catheter manipulations during daily dressing changes (Roldaan, Bosch, Eggink, & Van Leusen, 1990).

The length of time that a catheter should be covered with a sterile dressing (referred to as duration of sterile dressing) following catheter insertion has not been the subject of investigation. It is apparent from a review of protocols for the care of healed exit-sites that the length of time that the catheter is covered by a sterile dressing varies significantly (Clayton et al., 1981; Copely, 1987; Davis & Lavenders, 1980; Fuchs, et al., 1990; Jensen et al., 1989; Kim et al., 1984; Levy et al., 1990; Luzar et al., 1990; Oreopoulous et al., 1987; Prowant et al., 1987).

Vas (1981b), commenting on the various protocols for the care of the catheter in CAPD, suggested that these protocols were based upon rituals serving only to instill the importance of sterility to the patient, rather than being based upon scientific knowledge. Therefore, a study of the nursing care of the peritoneal dialysis catheter during the initial post-operative period was indicated. In this retrospective study, the impact of the duration and frequency of sterile dressing changes on the development of exit-site infections was examined. Also, the care of the catheter during the initial post-operative period by nursing staff and the patient/family were reviewed. Although the results of research suggests that the surgical techniques used during implantation and the care of the healed exit-site will decrease the incidence of exit-site infections, little is known about the role of the initial post-operative nursing care. A better understanding of the factors related to the incidence of exit-site infections will assist in the development of protocols for the use, duration, and frequency of sterile dressings following catheter insertion, and in the identification of areas for further study.

Summary

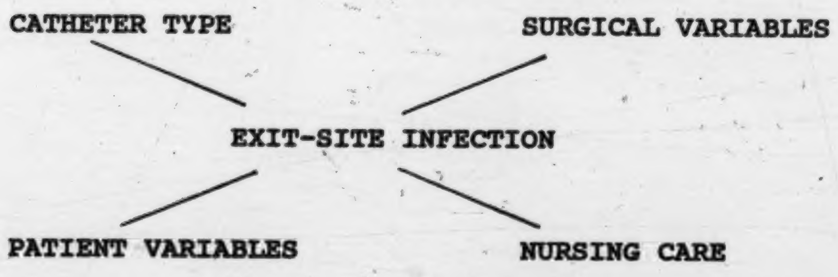
The success of peritoneal dialysis is dependent upon the prevention of infections, namely, peritonitis and catheter exit-site infections. Technological advancements have decreased the risk of peritonitis from accidental contamination of the dialysis solution. However, catheter exit-site infections remain a significant complication of treatment with CAPD. Clinical research has addressed catheter structure and surgical insertion techniques, and methods used in the care of healed exit-sites have been considered. See figure 2.1 for a diagrammatic depiction of the variables related to the development of peritoneal dialysis catheter exit-site infections. However, research into the care of the catheter in the initial post-operative period has been largely ignored.

Nurses are responsible for performing sterile dressing changes on the catheter in the initial post-operative period, and frequently, patients and/or family members are taught to perform the dressing change procedure to facilitate the patient's return home. Sterile dressing procedures and nursing care practices must be subjected to ongoing investigation to determine the most appropriate method of handling of the catheter by nurses during the initial post-operative period. It is imperative that nursing protocols and practices are based upon a scientific rationale to ensure that high quality of nursing care is provided. Nurses can no longer base procedures and practices upon tradition and/or individual preferences.

Figure 2.1. Factors identified from the literature as being associated with the development of peritoneal dialysis catheter exit-site infections.

- single/double cuff
- silastic/gortex

- percutaneous/ surgical insertion
- location of catheter
- direction of catheter's tunnel
- suture material at the exit-site
- antibiotics


CATHETER TYPE
SURGICAL VARIABLES
EXIT-SITE INFECTION
PATIENT VARIABLES
NURSING CARE

- age
- gender
- co-morbid conditions
- person's ability to see the catheter's exit-site
- Staphylococcal aureus nasal carriage

- healed exit-site care
- wearing of a dressing on a healed exit-site
- post-operative sterile dressing change frequency
- length of time sterile dressings are used to cover the exit-site

III. METHODS

The purpose of this chapter is to describe the methodology used in the research project. The chapter begins with a description of the final sample followed by a discussion regarding data collection procedures and the instrument used for data collection. The attained statistical power based upon the sample size is described. The methods used for data analysis are outlined, as are the mechanisms used for ensuring reliability and validity of the instrument and reliability of coding. The chapter concludes with a description of ethical considerations.

Description of the Sample

Sample

The population chosen for the study included those persons with end-stage renal disease who are/were treated with CAPD, and who are/were followed by a Chronic Renal Failure Program in Northern Alberta, Canada. Eligible for inclusion were adults (aged 18 years and older) who received an initial peritoneal dialysis catheter at the hospital from which the program is based, between the period of January 1985 and January 1990. Patients who required catheter reinsertions following removal due to peritonitis and/or exit-site infection were excluded from the sample, since the infectious process may not have been completely resolved, and therefore, may have influenced the subsequent development of exit-site infections associated around the new catheter. Patients who had their catheter removed prior to a six month duration of treatment without a documented exit-site infection were also excluded from analysis.

The final sample consisted of 130 persons who ranged in age from 18 to 80 years (mean age = 51.36, SD = 16.78). Males comprised 55.4% (72 people) of the sample, while females comprised the remaining 44.6% (58 people). The characteristics of the sample are similar to those of Canadian CAPD patients as reported by the Canadian Organ Replacement Register (1989). During the study period (January 1985 until January 1990), 213 people entered the peritoneal dialysis program. Of these, 83 (38.9%) did not meet the study's criteria, and therefore, were excluded from analysis. Reasons for exclusion can be found in Table 3.1.

Table 3.1

Reasons for Exclusion from the Study.

Reason for exclusion	Frequency	%
Aged less than 18 years at the time of catheter insertion	21	9.8
Catheter inserted and person nursed in another hospital	37	17.4
Catheter removed or person died prior to a six month duration following catheter insertion	23	10.8
Unable to access or located a person's medical records	2	0.9

(n = 83)

Statistical Power

The power of the chi-square analysis for the majority of the equations with a sample size of 130 and assuming a moderate effect size, ranges between 0.91 and 0.68, for tests with one to six degrees of freedom respectively (Cohen, 1977). However, two equations relating to the frequency of dressing changes during the individual post-operative weeks encompass nine degrees of freedom. Therefore, estimation of statistical power for these equations decreases to 0.60.

The two logistic regression equations attempted only involved the variables that were identified as being statistically significant through the use of chi-square. The estimated statistical power of the logistic regression equations, again assuming a moderate effect size with a sample of 130 was 0.97 (Cohen, 1977).

Data Collection

The research design used was a population based case-control study of the efficacy of therapy. The medical records of CAPD patients were used to identify factors contributing to the development of peritoneal dialysis catheter exit-site infections. Patients' charts were categorized according to presence or absence of the outcome (exit-site infection) within two time frames. These time frames were from catheter insertion until six months, and then from six months to one year following catheter insertion.

The data collection was done retrospectively and utilized secondary information obtained from the in-patient and out-patient medical records. Data collection was the responsibility of the investigator, and took place during a four month period, from December 1990 until March 1991.

Instrument

All information was collected using a data collection instrument designed by the investigator (see Appendix A). The items on the instrument were generated by the investigator from factors identified in the literature as being related to the development of exit-site infections. Some demographic data were collected and are used to describe the population. Prior to its use, the instrument was reviewed by an expert panel.

Face and content validity of the data collection instrument were assessed with the assistance of the expert panel. The expert panel was composed of three nurses and one physician who had experience with CAPD and the care of the person with a peritoneal dialysis catheter. They reviewed the data collection instrument on two occasions, first to review the instrument as initially developed by the investigator, and then, to review the revised instrument.

Assessment of face validity of each item was conducted by having the panel members identify whether each item was clear, reasonable, and acceptable for inclusion. Content validity of the items was assessed by examining the relevance and representativeness of the items to the area of peritoneal dialysis catheter exit-site infections. There was 100% agreement between the members of the panel regarding all the items contained in the instrument as developed by the investigator. The panel also assessed the content validity of the instrument as a whole, by indicating whether the instrument addressed all the possible factors influencing the development of peritoneal dialysis catheter exit-site infections. Members of the expert panel suggested the addition of two items (bacteriologic culture of exudate at time of exit-site infection and time until the performance of the initial post-operative dressing change) to the data collection instrument. Agreement was sought and obtained from the remaining panel members regarding these additions in the second review of the instrument by the panel. Following completion of the reviews of the instrument by the expert panel, pilot testing of the instrument was done using the medical records of 20 subjects. Minor changes in the instrument were made following the pilot testing. These changes addressed difficulties encountered in the coding of the data on the form, and served to simplify data collection from the medical records.

The reliability of the data collection was enhanced through the use of one data collector, namely the investigator. Intra-rater reliability was assessed by randomly checking 10% of the charts three weeks after initial data collection. In each of these records, there was 95% agreement between the data that was collected on the first and second review of the medical records. In addition, all data entry was done by the investigator. Reliability of the data entry was tested by randomly checking 20% of the completed instruments with the computer coding of the data prior to statistical analysis. There was complete agreement between those data collection instruments randomly checked and the computer coding of the data.

Data Analysis

The dependent variable in the study was expressed categorically, in that the subject was designated as either a case or a control, based on the documented presence of an exit-site infection within the two time periods. In addition, most of the independent variables were dichotomous and categorical. For these reasons, the most effective method of analysis was from simple to complex (Kramer, 1988). The cases and the controls were unmatched except for length of time since catheter insertion; therefore, statistical analysis of the exposure variables served to identify whether a relationship existed between exposure to the variable and the development of an exit-site infection.

Statistical analysis was facilitated by the construction of tables, crosstabulating the dependent variable with each of the independent variables. Odds ratios were calculated for each dichotomous independent variable. In addition to the determination of the odds ratio for these variables, the tables were used in the analysis of tests of significance. Significance was determined by the chi-square test for association with each independent variable and the outcome, testing against a null hypothesis of no association. Following identification of the statistically significant independent variables through the use of chi-square analysis, logistic regression was done using only those independent variables that were identified as being statistically significant with the outcome through the use of chi-square analyses. Two logistic regression equations were attempted (exit-site infections developing during the initial six months and then exit-site infections developing during the initial year following insertion).

Ethical Considerations

Appropriate institutional and ethical approvals were obtained before beginning the study. To ensure confidentiality, the investigator designed a coding system for the instruments following access of the patient record using the hospital's identification numbering system. The relationship between the hospital numbering system and that of the sample is known only to the investigator. Access to the data was limited to the investigator by virtue of placing the information in a locked filing system. In addition, any dissemination of information has and will not identify specific subjects. Only grouped data will be reported.

Following final analysis of the data, all code lists and data collection forms have been destroyed by the investigator. Computer data files, without identifying information, will be kept for five years, after which time the files will be destroyed. No further analysis of these data are planned. However, in the event such analysis is desired by the investigator or others, consent will be obtained from appropriate ethics committees.

IV. RESULTS

The findings of the study are organized according to the research questions. Data analysis was facilitated through the entry of the data into a computer file (MTS System EP190, University of Alberta computing systems) by the investigator. Statistical analysis was done using SPSS-X Release 3.0 software 1988 release, and logistic regression using BMDP statistical software 1987 release.

Because it was thought that influence of post-operative nursing care would be stronger in months immediately following catheter insertion, the data were divided into two subgroups following the initial analyses of the whole data. These subgroups were: firstly, those persons who developed an exit-site infection during the first six months following catheter insertion compared to those persons who did not develop an exit-site infection in that time period; and secondly, those persons who developed an exit-site infection during the latter six months of the initial year following catheter insertion compared to those persons who remained with a peritoneal catheter for one year following insertion and who did not develop an exit-site during the initial year following catheter insertion. The analyses pertaining to the two time periods are presented only when a significant difference was identified between the association of the variable with the outcome. Otherwise, the results presented reflect data obtained for all subjects for the entire one year time frame.

Description of the Sample

Cases/Controls

Fifty-eight people developed exit-site infections during the year following catheter insertion. This group comprised the cases, and analysis was done by the comparison of these cases with the controls. The remaining 72 people who did not develop an exit-site infection during the first year following catheter insertion were considered to be controls.

Incidence of Exit-site Infection

The cumulative incidence for exit-site infection during the initial year was 44.6%. The breakdown of exit-site infections for individual months of the initial year following catheter insertion is described in Table 4.1.

Table 4.1

Cumulative Incidence of Exit-site Infection.

Length of time from insertion in months	# of new cases	Incidence in percentage
1	16	12.3
2	10	20.0
3	5	23.8
4	4	26.9
5	3	29.2
6	6	33.8
7	2	35.4
8	3	37.7
9	2	39.2
10	2	40.8
11	3	43.1
12	2	44.6

(n = 130)

Although the definition of an exit-site infection was not dependent upon the existence of a positive culture, the majority (49 infections, 84%) of the cases were cultured at the time of antibiotic prescription. In this sample, the major causative organisms of exit-site infection were coagulase-negative staphylococci. Culture results are presented in Table 4.2.

Table 4.2

Bacteriological Culture of Exit-site Infections.

Result	Frequency	%
Coagulase-negative Staphylococci	33	67.3
No growth	7	14.3
Pseudomonas aeruginosa	4	8.2
Streptococcus	1	2.0
Escherichia Coli	3	6.1
Normal Skin Flora	1	2.0

(n = 49)

Length of Treatment with CAPD

Sixty-seven patients (51.5%) continued to use CAPD for renal replacement therapy for a complete year following catheter insertion. The remaining 63 people (48.5%) withdrew from CAPD at various times throughout the year. Reasons for withdrawal included: transfer to hemodialysis (n = 26; 20%); successful kidney transplant (n = 24; 18.5%); death (n = 10; 7.7%);

transfer from the geographical area that the renal program served (n = 2; 1.5%); and recovered kidney function (n = 1; 0.8%).

Thirty-eight of the patients (22%) had the peritoneal dialysis catheter removed within the year following catheter insertion. Eight catheters were removed following a successful kidney transplant, two because of dialysate leakage, and the remaining 28 catheters were removed as a result of infection. Of these 28 catheters removed because of infection, 12 patients had unresolved exit-site infections, while the other 16 had repeated episodes of peritonitis. Only 12 of these 28 catheters removed because of infection (exit-site or peritonitis), were reinserted. The remaining 18 patients were transferred to treatment with hemodialysis.

Year of Catheter Insertion

All subjects had a peritoneal dialysis catheter inserted during the five year period, from January 1985 to December 1989 (see Figure 4.1). There was no difference in the incidence of exit-site infections dependent upon the year that the subject had his or her peritoneal catheter inserted, [χ^2 (4, N = 103) =.57, p = 0.63, minimum expected frequency = 9.37].

Previous Treatment for Renal Failure

The majority of the sample, 73 subjects (56.2%) had been treated with hemodialysis prior to peritoneal catheter insertion (see Figure 4.2). For the most part, hemodialysis was used to stabilize the person with end-stage renal disease prior to surgery and/or to facilitate the decision-making process regarding treatment. Only three individuals received hemodialysis or were transplanted for a period of greater than one year prior to peritoneal dialysis catheter insertion. Previous and/or concurrent treatment for renal disease by hemodialysis and transplantation was not related to the development of exit-site infection [χ^2 (3, N = 130) = 1.80, p = 0.62, minimum expected frequency (EF) = 2.23, cells with EF < 5 = 4 (50%)].

Cause of Renal Failure

The subjects' renal failure resulted from a variety of systemic and/or renal diseases. The cause of renal failure could not be determined for 22 subjects (16.9% of the sample). These persons presented for treatment with end-stage renal disease requiring dialysis therapy and kidney biopsy was not performed. In the remaining 108 subjects, glomerulonephritis and diabetes were the most common causes of renal failure, affecting 29.2% and 21.5% of the sample respectively. The complete description of the causes of renal failure in the sample are contained in Table 4.3.

Table 4.3.

Cause of Renal Failure

Cause	Frequency	%
Glomerulonephritis	38	29.2
Diabetes	28	21.5
Unknown	22	16.9
Hypertension	6	4.6
Polycystic Disease	6	4.6
Renal Cancer	4	3.1
Other*	26	20.0
(n = 130)		

Note: * includes amyloidosis, scleroderma, lupus, renal artery stenosis, etc.

Figure 4.1. The development of exit-site infections according to the year of catheter insertion.

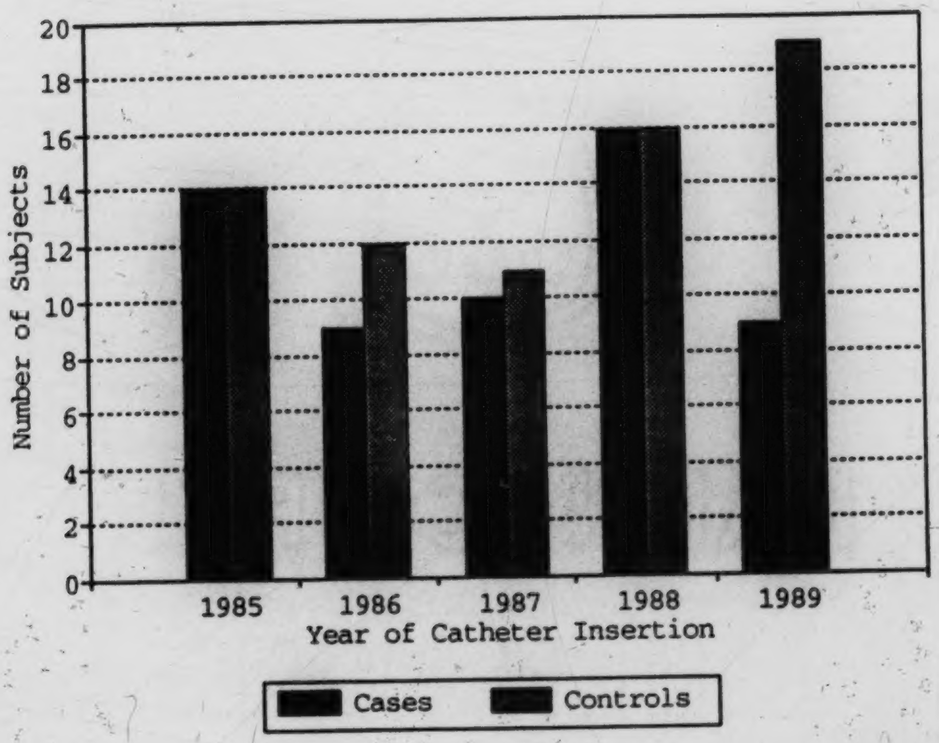
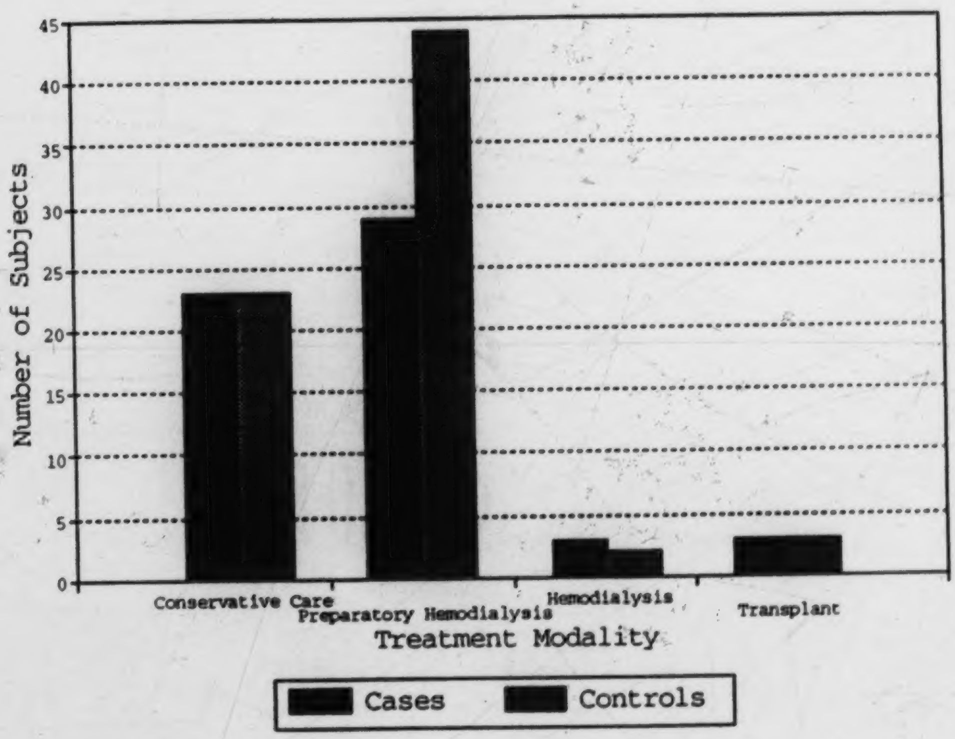


Figure 4.2. Exit-site infection development during the initial year following catheter insertion in relation to previous and/or concurrent treatment for end-stage renal disease.



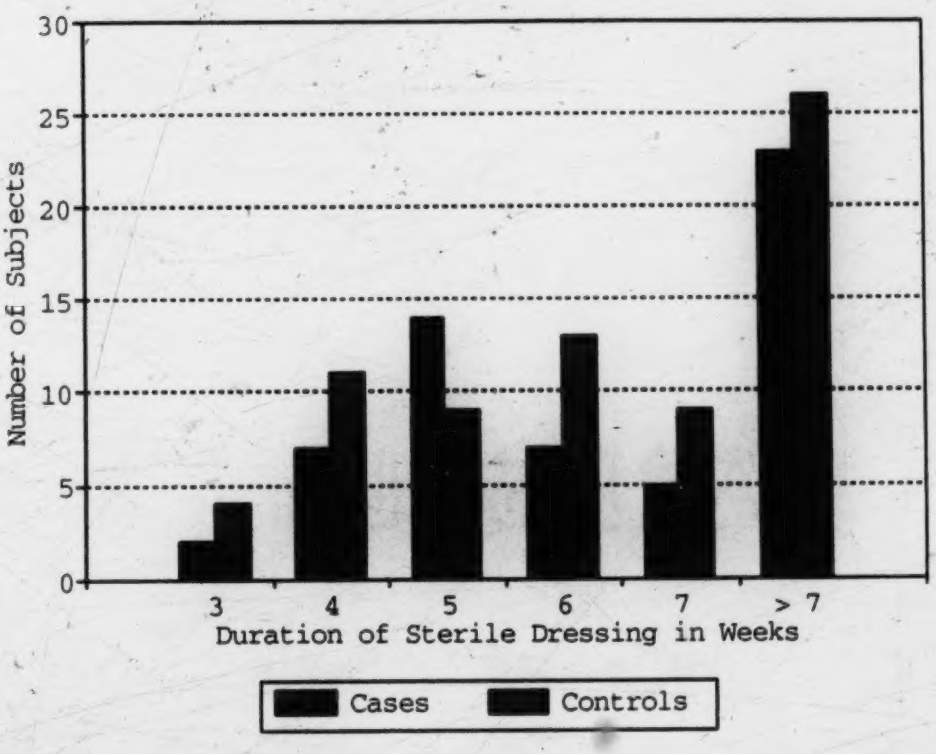
Post-Operative Sterile Dressings

The first research question addressed the possible influence of the duration and/or frequency of dressing changes on the development of exit-site infections. The incidence of exit-site infections during the initial year following catheter insertion was 44.6%. The 58 people who had an exit-site infection during that year are compared to those 72 people who remained free from exit-site infection in relation to the duration and frequency of sterile dressings.

Duration of Sterile Dressings

The duration of sterile dressing changes ranged from three weeks to greater than seven weeks post-operatively. The median duration of sterile dressings used post-operatively was six weeks, with 48.5% (63 subjects) continuing to perform sterile dressing changes on the peritoneal dialysis catheter for seven or more weeks following catheter insertion. Ten subjects continued sterile dressings for months following catheter insertion. One person continued using sterile dressings on the catheter for five months following catheter insertion. Figure 4.3 depicts the

Figure 4.3. Duration of sterile dressings in relation to the development of exit-site infections during the initial year following catheter insertion.



distribution of cases and controls in relation to the duration of sterile dressings covering the catheter. There was no significant relationship between the development of exit-site infections and the duration of sterile dressing changes to the catheter [χ^2 (5, N = 130) = 4.31, p = 0.51, minimum expected frequency (EF) = 2.68, cells with EF < 5 = 2 (16.7%)].

Sterile Dressing Frequency

There was a wide variation in the frequency of sterile dressing changes recorded during the first seven weeks following catheter insertion. No set routines for changing sterile dressings were apparent; nurses changed the dressing whenever they considered it appropriate.

The data regarding this question became unavailable when the person was discharged and began to perform the sterile dressing changes at home. Therefore, the size of the sample decreased accordingly, and the number of missing cases increased. Some patients were discharged from the hospital, and then were subsequently readmitted thereby permitting further data collection. The frequency of dressing changes for each of the post-operative weeks can be found in Figures 4.4 through 4.10.

The frequency of dressing changes during the individual weeks was not related to the development of exit-site infections during the initial year following catheter insertion (see Table 4.4). However, there was a statistically significant association between the frequency of dressing changes performed in the first post-operative week and the development of exit-site infections within six months of catheter insertion [χ^2 (8, N = 130) = 16.63, p = 0.03, minimum expected frequency (EF) = 0.35, cells with EF < 5 = 10 (55.6%)] (see Table 4.5). The comparison of cases and controls in relation to the frequency of sterile dressing changes performed during the initial post-operative week are contained in Figure 4.11.

There was no association between the development of exit-site infections during the latter half of the initial year following catheter insertion and the frequency of sterile dressings performed during any of the weeks of the initial post-operative period (see Table 4.6).

Figure 4.4. The frequency of sterile dressings performed on the catheter during the first post-operative week in relation to the development of exit-site infections during the initial year following catheter insertion.

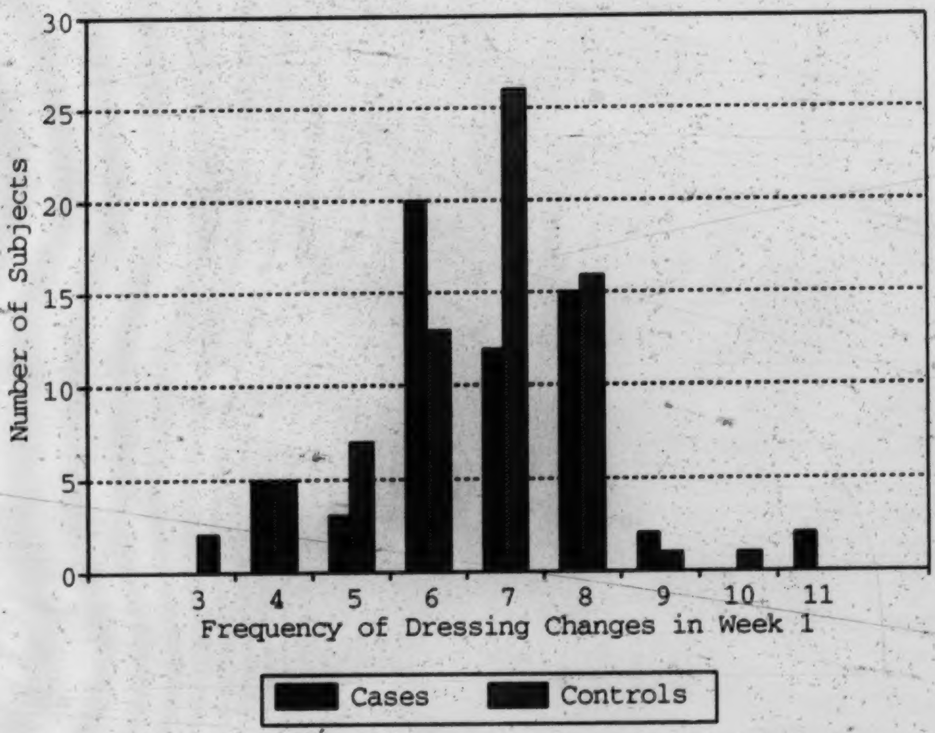


Figure 4.5. The frequency of sterile dressings performed on the catheter during the second post-operative week in relation to the development of exit-site infections during the initial year following catheter insertion.

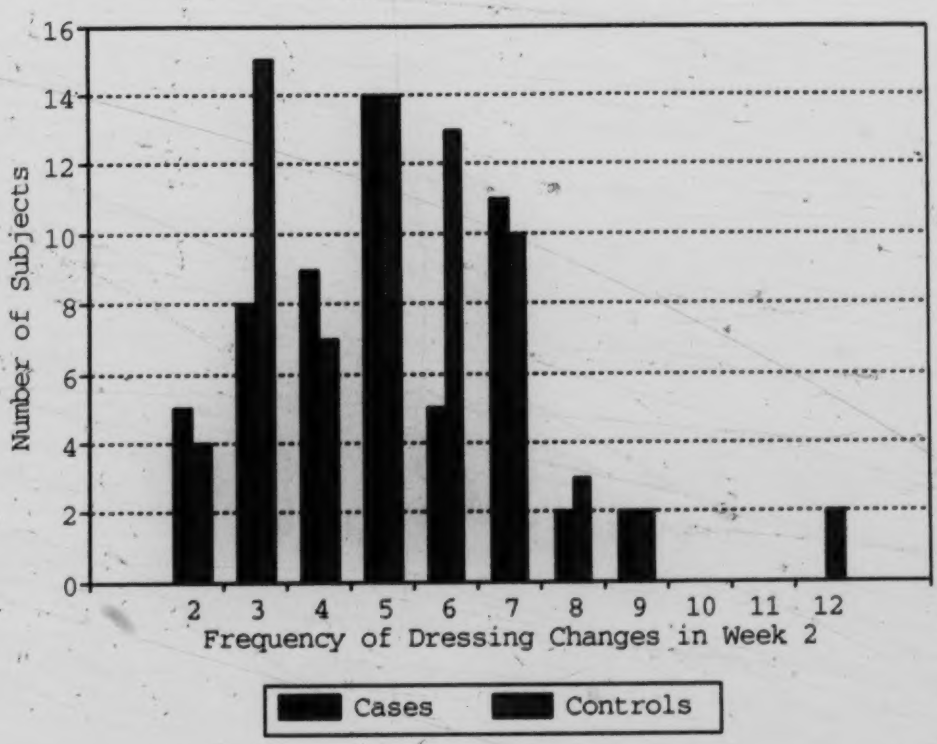


Figure 4.6. The frequency of sterile dressings performed on the catheter during the third post-operative week in relation to the development of exit-site infections during the initial year following catheter insertion.

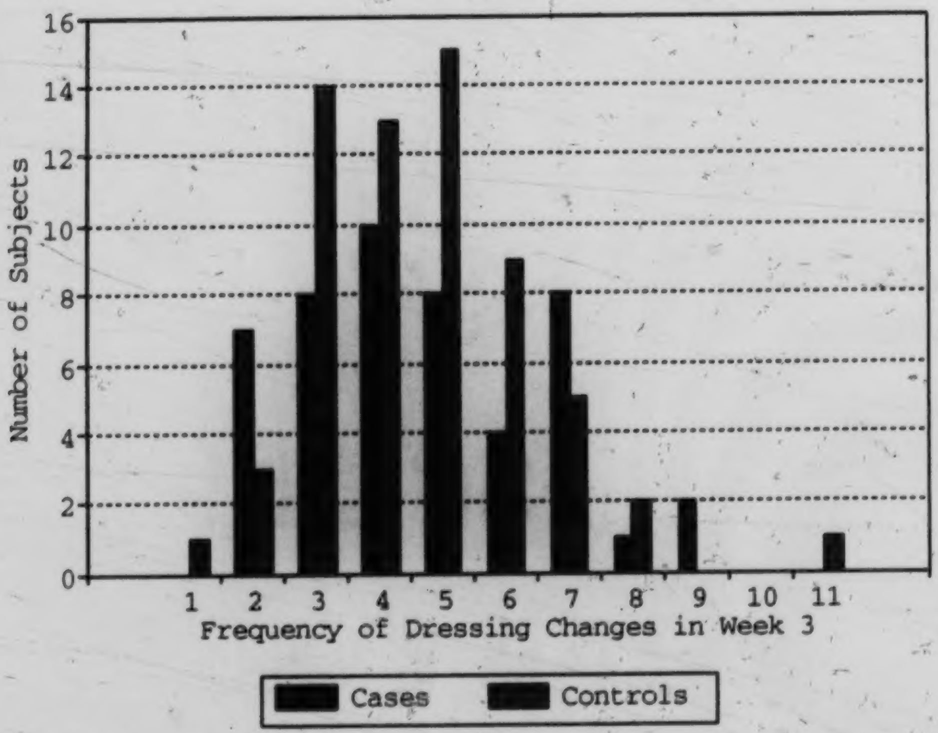
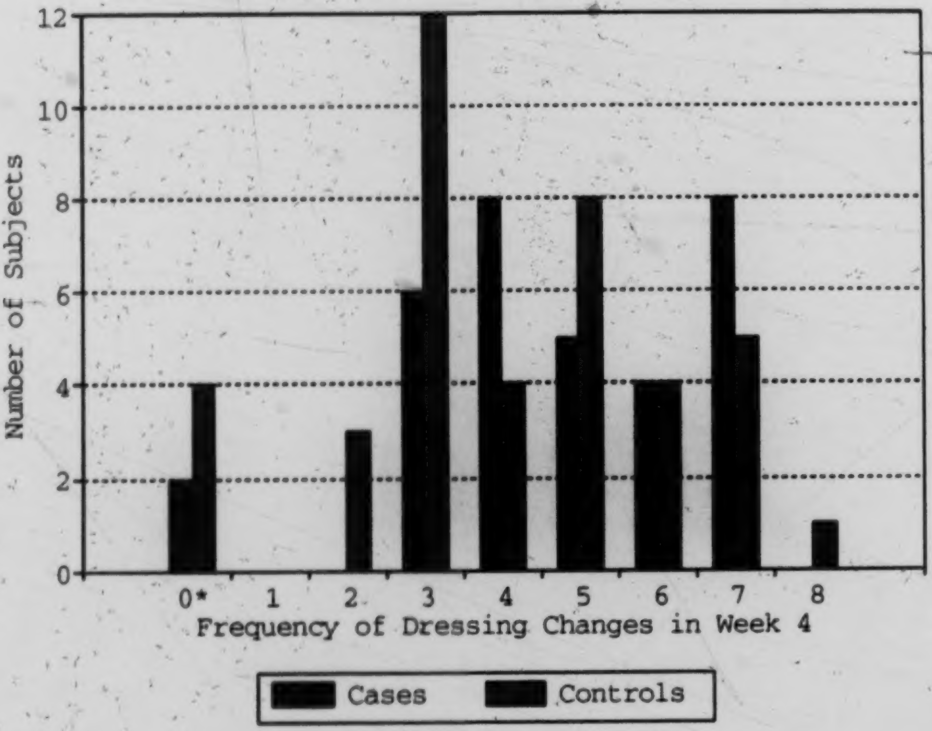
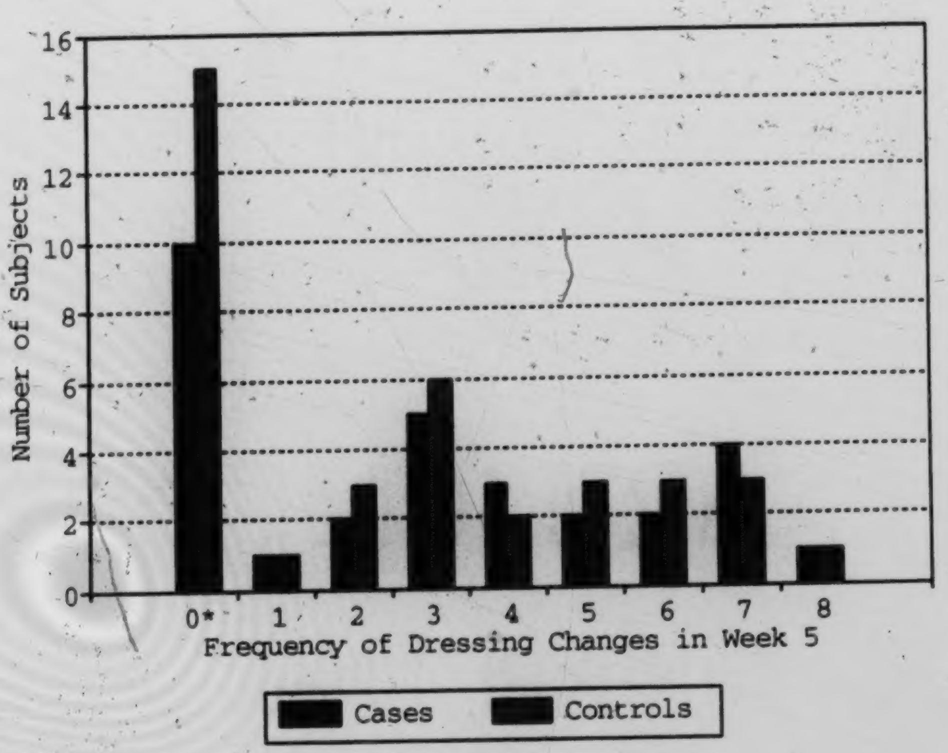


Figure 4.7. The frequency of sterile dressings performed on the catheter during the fourth post-operative week in relation to the development of exit-site infections during the initial year following catheter insertion.



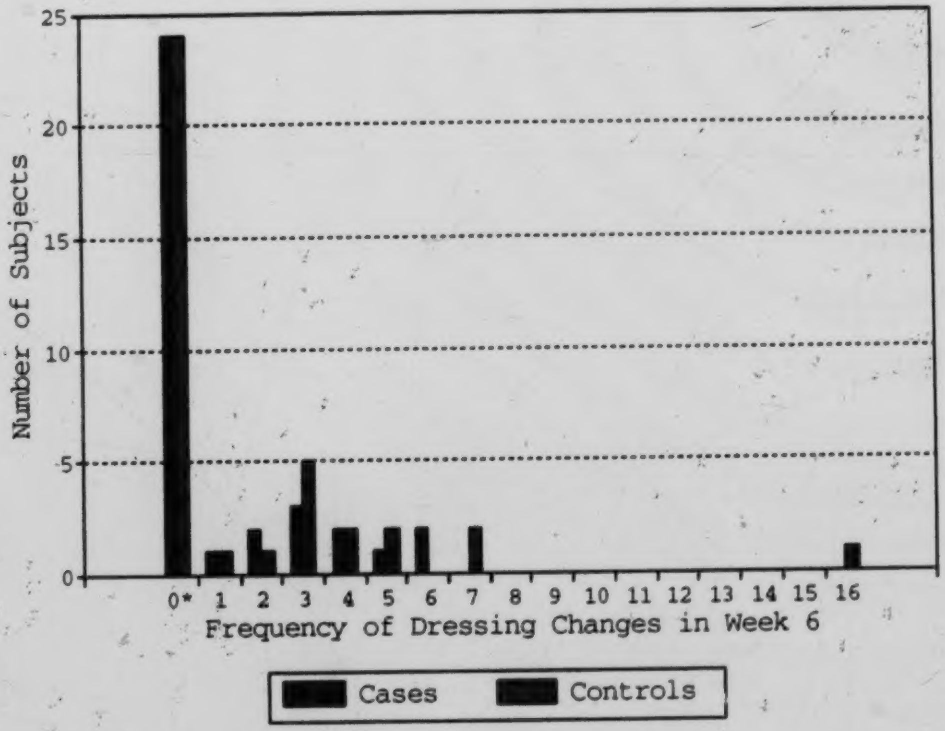
Note: * denotes subjects who have commenced healed exit-site care.

Figure 4.8. The frequency of sterile dressings performed on the catheter during the fifth post-operative week in relation to the development of exit-site infections during the initial year following catheter insertion.



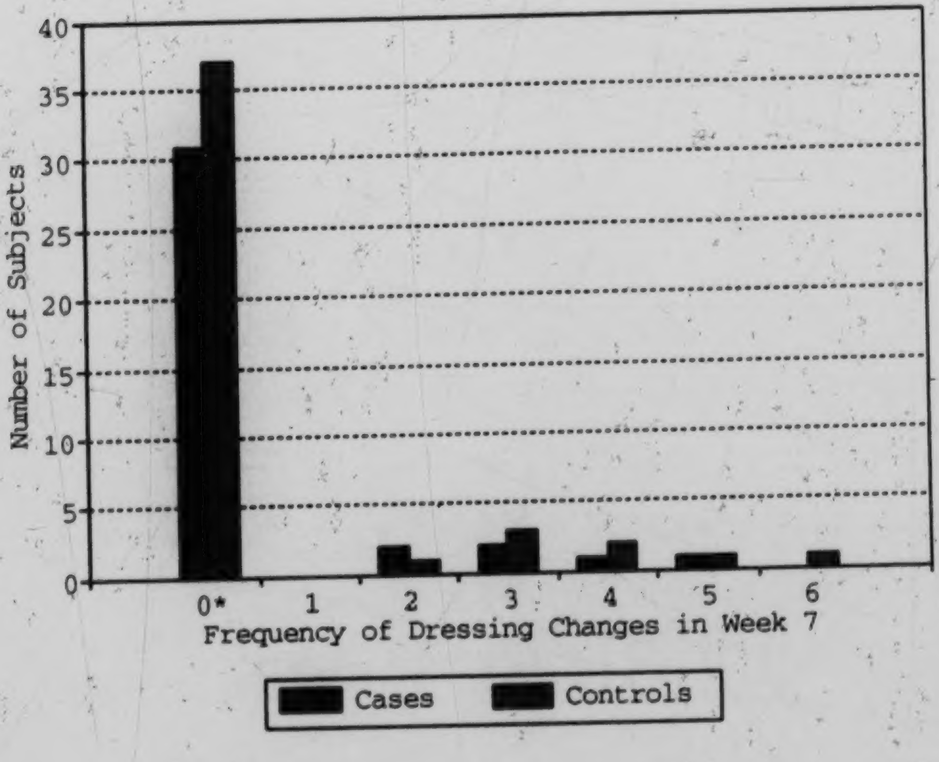
Note: * denotes subjects who have commenced healed exit-site care.

Figure 4.9. The frequency of sterile dressings performed on the catheter during the sixth post-operative week in relation to the development of exit-site infections during the initial year following catheter insertion.



Note: * denotes subjects who have commenced healed exit-site care.

Figure 4.10. The frequency of sterile dressings performed on the catheter during the seventh post-operative week in relation to the development of exit-site infections during the initial year following catheter insertion.



Note: * denotes subjects who have commenced healed exit-site care.

Table 4.4.

The frequency of sterile dressing changes performed during each week of the initial post-operative period in relation to the development of exit-site infections during the initial year following catheter insertion.

Week	M ± SD	χ^2	df	p	% of cells with EF < 5
one	6.67 ± 1.4	12.24	8	0.14	55.6
two	5.13 ± 1.9	6.82	8	0.56	38.9
three	4.65 ± 1.8	10.88	9	0.28	45.0
four	4.32 ± 2.0	8.62	7	0.28	50.0
five	2.71 ± 2.7	1.32	8	0.99	83.3
six	1.43 ± 2.6	6.05	8	0.64	88.9
seven	0.59 ± 1.4	1.63	5	0.90	83.3

Figure 4.11. The frequency of sterile dressing changes performed during the first post-operative week in relation to the development of exit-site infections within six months of catheter insertion.

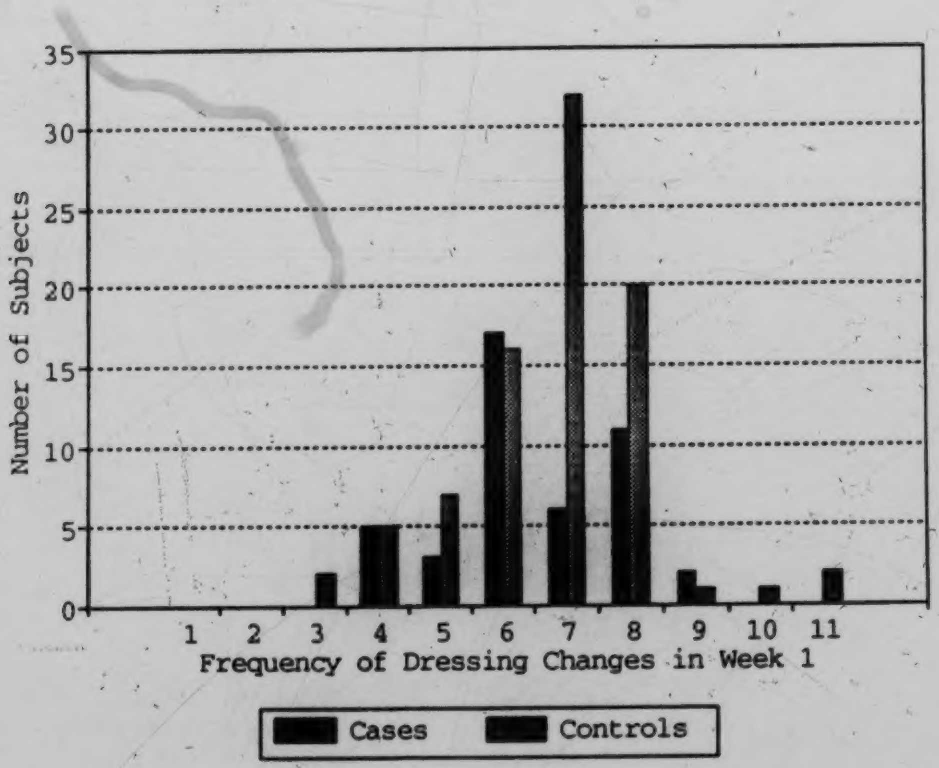


Table 4.5.

The frequency of sterile dressing changes performed during each week of the initial post-operative period in relation to the development of exit-site infections within six months of catheter insertion.

Week	M ± SD	χ^2	df	p	% of cells with EF < 5
one	6.67 ± 1.4	16.63	8	0.03*	55.6
two	5.13 ± 1.9	6.02	8	0.64	38.9
three	4.65 ± 1.8	13.04	9	0.16	55.0
four	4.32 ± 2.0	8.13	7	0.32	62.5
five	2.71 ± 2.7	2.09	8	0.98	83.3
six	1.43 ± 2.6	8.96	8	0.35	88.9
seven	0.59 ± 1.4	3.63	5	0.60	83.3

Note: * statistically significant at $p \leq 0.05$.

Table 4.6.

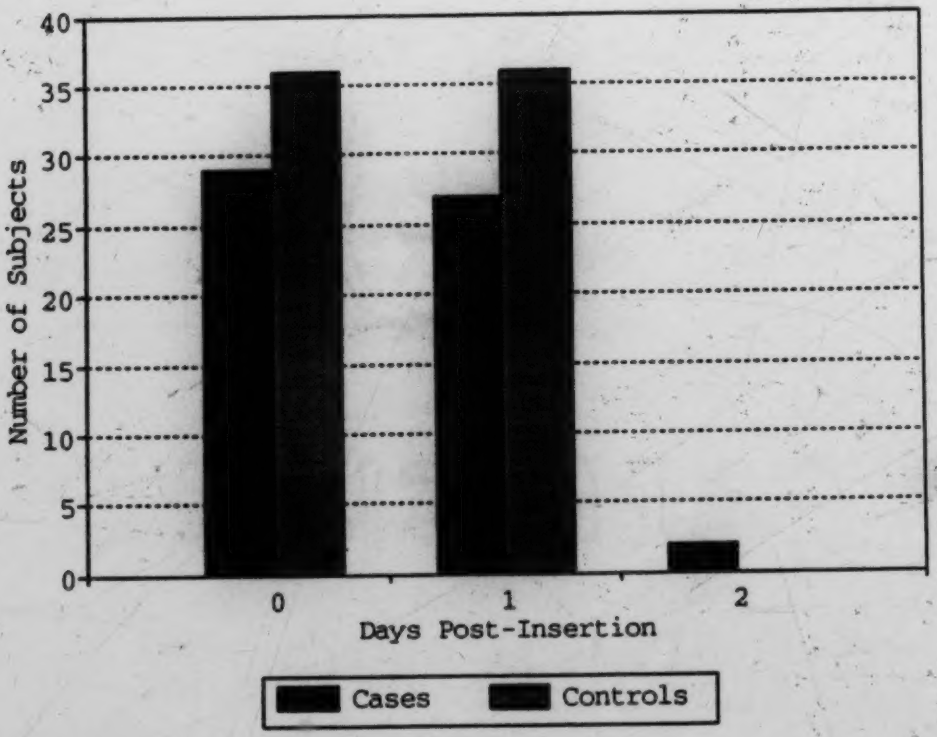
The frequency of sterile dressings performed on the catheter during the initial post-operative period in relation to the development of exit-site infections during the latter six months of the initial year.

Week	M ± SD	χ^2	df	p	% of cells with EF < 5
one	6.70 ± 1.4	4.99	7	0.66	75.0
two	5.21 ± 2.1	11.34	8	0.18	77.8
three	4.58 ± 1.8	9.39	8	0.31	77.8
four	3.80 ± 2.1	4.71	7	0.70	93.8
five	2.57 ± 2.7	7.55	8	0.48	94.4
six	1.41 ± 2.1	1.41	6	0.97	92.9
seven	0.66 ± 0.5	2.40	4	0.66	80.0

Time of Initial Post-operative Dressing

Half (n = 65) of the subjects had their initial post-operative dressing change done on the day of surgery. Only two individuals had the initial post-operative dressing left undisturbed for 48 hours (see Figure 4.12). However, the odds ratio comparing the risk of having the initial sterile dressing change performed on the day of surgery (1.0) and chi-square analysis, [χ^2 (2, N = 130) = 2.56, p = 0.28, minimum expected frequency (EF) = 0.89, cells with EF < 5 = 2 (33.3%)], does not suggest that subjects who had their post-operative dressing change performed on the day of surgery were more at risk of developing an exit-site infection than those subjects for whom the dressing was left undisturbed for at least 24 hours post-surgery.

Figure 4.12. Length of time from surgery until the initial post-operative dressing change is performed on the peritoneal dialysis catheter.



Persons Performing the Sterile Dressing Change

The second research question addressed the relationship between the person (i.e., patient/family/nurse) performing the sterile dressing change procedures and the development of exit-site infections. In the data analysis, patients were compared with nurses and/or family members, family members were compared with nurses and/or patients; and lastly, nurses were compared with patients and/or family members. Results of analyses obtained from odds ratio calculations for each grouping are found in Table 4.7.

Table 4.7.

The risk of developing an exit-site infection during the initial year following catheter insertion dependent upon the person who performed sterile dressing change procedures during the initial post-operative period.

Factor	Comparison	Odds Ratio	total # of subjects
Patients	patients nurses/family	0.94	75 55
Family	family nurses/patients	1.19	27 103
Nurses	nurses patients/family	1.33	36 98

Seventy-five patients were taught sterile dressing procedures during the initial post-operative period. Of these, 33 (44%) developed an exit-site infection during the first year following catheter insertion. There did not appear to be a statistically significant association between the performance of sterile dressing changes by patients during the initial post-operative period and the development of exit-site infections [χ^2 (1, N = 130) = 0.03, p = 0.87, minimum expected frequency = 24.54].

In addition, although the odds ratio (1.19) suggests a slightly increased risk for exit-site infection when family members assume dressing procedures (see Table 4.7), there was not a statistically significant association between this variable and the outcome variable [χ^2 (1, N = 130) = 0.17, p = 0.68, minimum expected frequency = 12.05].

Conversely, in the group of patients (n = 36) for whom nurses were solely responsible for performing dressing changes on the peritoneal dialysis catheter during the initial post-operative period, the risk of developing an exit-site infection (1.33) was higher than the risk for the group of patients where patients and/or family members assumed responsibility for the performance of the dressing procedures (see Table 4.7). However, chi-square analysis did not show a statistically significant association between this variable and the outcome [χ^2 (1, N = 130) = 0.50, p = 0.48, minimum expected frequency = 14.28].

When the analysis was repeated defining cases as those persons who developed an exit-site within six months of catheter insertion, the risk of developing an exit-site infection when only nurses were responsible for performing the sterile dressing changes is double that of the group where patients and/or family members assumed responsibility for the dressing changes (see Table 4.8). However, chi-square analysis of this variable, limiting the performance of sterile dressing change procedures to nurses did not identify a statistically significant association between the variable and the outcome [χ^2 (1, N = 130) = 2.82, p = 0.09, minimum expected frequency = 11.08].

Table 4.8.

The risk of developing an exit-site infection within six months of catheter insertion dependent upon the person who performed sterile dressing change procedures during the initial post-operative period.

Factor	Comparison	Odds Ratio	total # of subjects
Patients	patients nurses/family	0.58	75 55
Family	family nurses/patients	1.39	27 103
Nurses	nurses patients/family	2.00	36 98

Time Until Patient/Family Performs Sterile Dressings

Patients and/or family members commenced the performance of sterile dressings at various points during the initial post-operative period. Typically, the procedures were taught to the patient and/or family member in anticipation of discharge from hospital, or during the training period for CAPD. Patients and/or family members commenced the performance of sterile dressing changes on the catheter between the fourth and 39th day following surgery (see Figure 4.13). On average, patients and/or family member were taught to do sterile dressings on the 18th post-operative day (M = 17.86, SD = 7.40).

There did not appear to be a statistically significant association between the development of exit-site infections within the initial year following catheter insertion and the length of time post-operatively after which the patient and/or family member commenced the performance of sterile dressing changes on the peritoneal dialysis catheter [χ^2 (5, N = 98) = 6.71, p = 0.24, minimum expected frequency (EF) = 0.86, cells with EF < 5 = 6 (50%)]. However, when the comparison was repeated using exit-site infections that had developed within six months of catheter insertion (see Figure 4.14), the length of time post-operatively that the patient and/or family member commenced the performance of the sterile dressings on the catheter had a statistically significant association with the outcome of exit-site infections [χ^2 (5, N = 98) = 15.12, p = 0.01, minimum expected frequency (EF) = 0.61, cells with EF < 5 = 5 (41.7%)].

Figure 4.13. The length of time post-operatively that the patient and/or family member commenced the performance of the sterile dressing changes on the peritoneal dialysis catheter in relation to the development of exit-site infections during the initial year following catheter insertion.

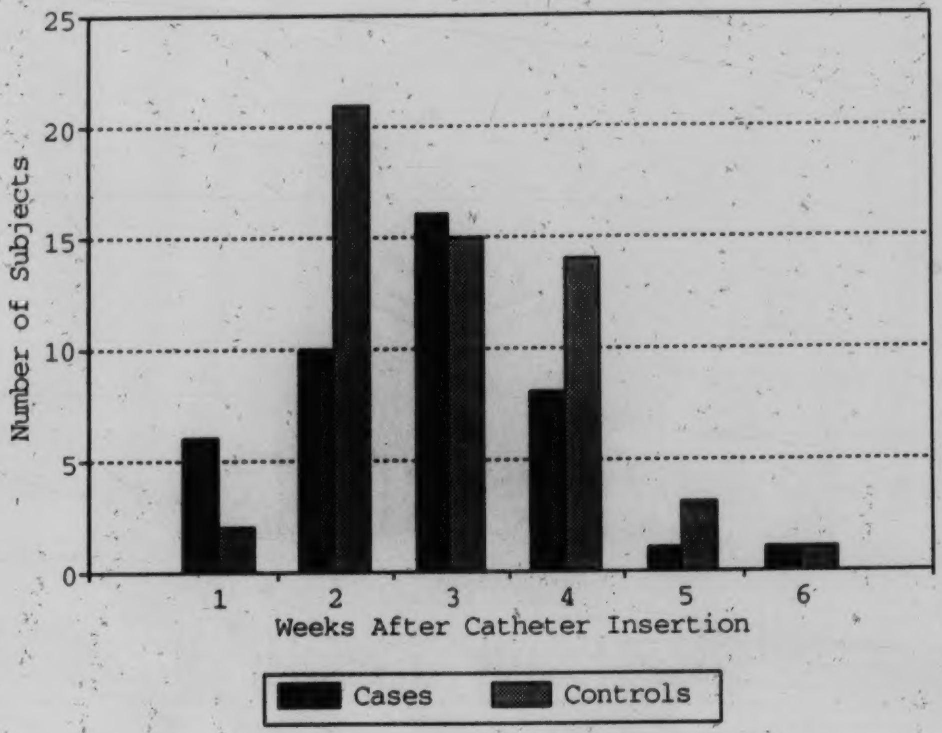
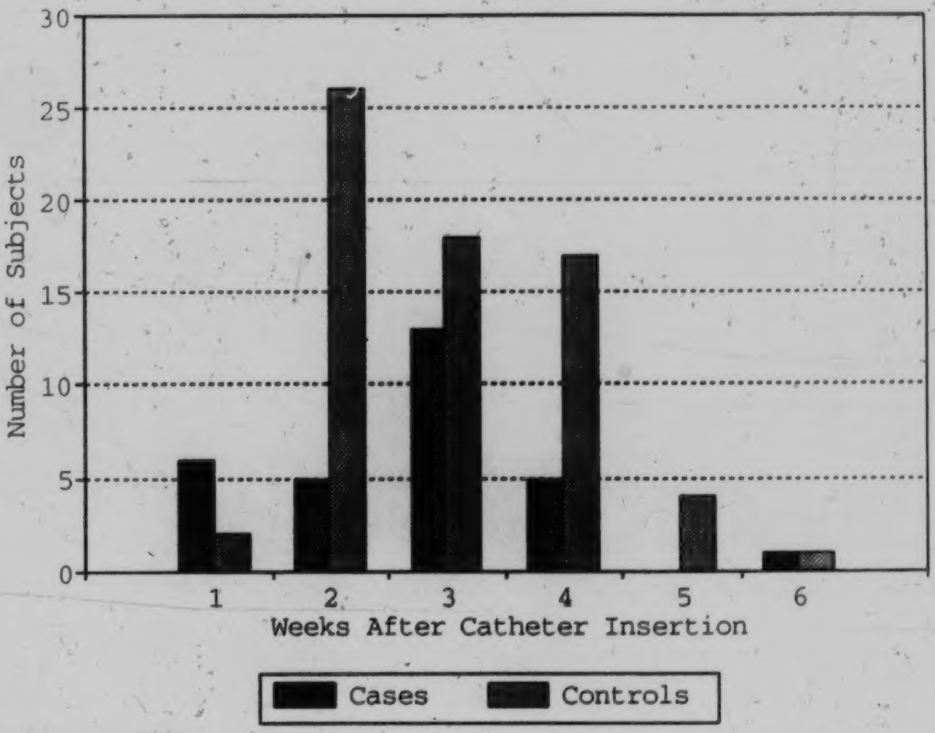


Figure 4.14. The length of time post-operatively that the patient and/or family member commenced the performance of the sterile dressing changes on the peritoneal dialysis catheter in relation to the development of exit-site infections within six months of catheter insertion.



Factors Related to Exit-Site Infections

The final research question pertained to the effect of any additional factors on the development of exit-site infections within this sample of CAPD patients. The factors considered included: patient characteristics (e.g., age, gender, visual impairment and/or co-morbid conditions); catheter insertion factors (e.g., catheter type, location of exit-site, direction of catheter tunnel, use of prophylactic antibiotics, and/or sutures at the exit-site); and procedural variables (e.g., type of germicidal solution used for sterile dressing changes, methods of healed exit-site care used, and/or length of time from catheter insertion until peritoneal dialysis commenced). The findings are discussed in relation to these groups of variables.

Patient Characteristics

This analysis considered those factors that were specific to the individual subjects when they had a peritoneal dialysis catheter inserted. Factors included the age and gender of the person, and possible co-morbid conditions and limitations that may affect the person's abilities to care for the catheter.

Age. Subjects ranged in age between 18 and 80 years, with a mean age of 51.36 (SD = 16.78). Distribution of cases and controls according to age is found in Figure 4.15. To facilitate analysis of the possible effect that age may play upon the development of exit-site infections, the sample was stratified into three age categories. These categories were young adults, aged 18 to 45 years; middle-aged adults, aged 46 to 65 years; and lastly, older adults, who were greater than 65 years of age. This stratification of ages was necessary to prevent the use of a large number of cells within the chi-square analysis for which the expected frequency would be less than five.

Odds ratios were calculated comparing older adults with middle-aged adults (1.15), older adults with young adults (0.99), and lastly, middle-aged adults with young adults (0.83). No age group was at greater risk of developing an exit-site infection than persons within the other age groups (see Table 4.9). In addition, no association between age and the development of exit-site infections was found using chi-square analysis [χ^2 (2, N = 130) = 0.16, p = 0.92, minimum expected frequency = 15.62].

__Gender__. The sample was comprised of 58 women and 72 men. Proportions of men and women who developed exit-site infections were similar, with 45.8% of the males and 43.1% of the females within the sample developing an exit-site infection (see Figure 4.16). Gender was not associated with an additional risk (Odds ratio 1.12) of exit-site infection (see Table 4.9). Nor, did the use chi-square analysis suggest a relationship between gender and the development of exit-site infection [χ^2 (1, $\underline{N}$ = 130) = 0.10, $\underline{p}$ = 0.76, minimum expected frequency = 25.87].

__Visual Impairment__. Subjects were considered to be visually impaired when there was a notation on the patient's chart regarding limited visual acuity, or a comment pertaining to difficulties in the learning of and/or performance of the CAPD procedures as a result of visual problems. Notations on the medical records regarding visual abilities were made by the dialysis nursing staff, the nephrologist, and in some instances by a consulting ophthalmologist.

Thirty-two subjects were classified as visually impaired using this definition. The limited vision of these individuals did seem to be related to the development of exit-site infections (see Figure 4.17). Subjects with limited vision had a slightly higher risk (Odds ratio = 1.33) of developing an exit site infection than those persons with adequate vision (see Table 4.9). However, analysis with chi-square did not indicate a statistically significant association between visual impairment and the development of exit-site infections [χ^2 (1, N = 130) = 0.50, p = 0.48, minimum expected frequency = 14.28].

Co-morbid Conditions. In the development of this research question, the investigator questioned whether or not the co-existence of other systemic diseases was related to the development of exit-site infections. Forty-six subjects (35.4%) were afflicted with co-morbid conditions in addition to end-stage renal disease (see Figure 4.18). The largest proportion of these patients were diabetics (38 subjects, 29.2% of the sample), while the remainder included one person each with rheumatoid arthritis, amyloidosis, and scleroderma; and lastly, there were four people with lupus erythematosus. Although the co-existence of these systemic diseases slightly increased the person's risk of developing an exit-site infection (see Table

4.9), a statistically significant association with the outcome was not found [χ^2 (1, N = 130) = 0.84, p = 0.36, minimum expected frequency = 20.52].

Twenty-four (63.2%) of the subjects with diabetes mellitus were insulin dependent at the time of catheter insertion. However, this subgroup of patients did not have an increased risk of exit-site infections (see Table 4.9). There was no evidence of a statistically significant association existed between the presence of insulin dependent diabetes and the development of exit-site infections [χ^2 (1, N = 130) = 0.02, p = 0.89, minimum expected frequency = 10.71]. Similarly, the co-existence of non-insulin dependent diabetes did not have a relationship with the development of exit-site infections [χ^2 (1, N = 130) = 1.64, p = 0.20, minimum expected frequency (EF) = 4.85, cells with EF < 5 = 1 (25%)].

Table 4.9.

The characteristics of the subjects in relation to the development of exit-site infections during the initial year following catheter insertion.

Patient Characteristics

Factor	Comparison	Odds ratio	total # of subjects
Age	> 65 years 46-65 years	1.15	30 50
	> 65 years 18-45 years	0.99	30 45
	46-65 years 18-45 years	0.83	50 45
Gender	Males Females	1.12	72 58
Vision	Impaired Normal	1.33	32 98
Co-morbid Condition	Present Absent	1.40	46 84
*Insulin-Dependent Diabetes	Present Absent	1.01	24 106

Note: * insulin dependence at the time of catheter insertion.

Figure 4.15. Subjects' age in relation to the development of exit-site infections during the initial year following catheter insertion.

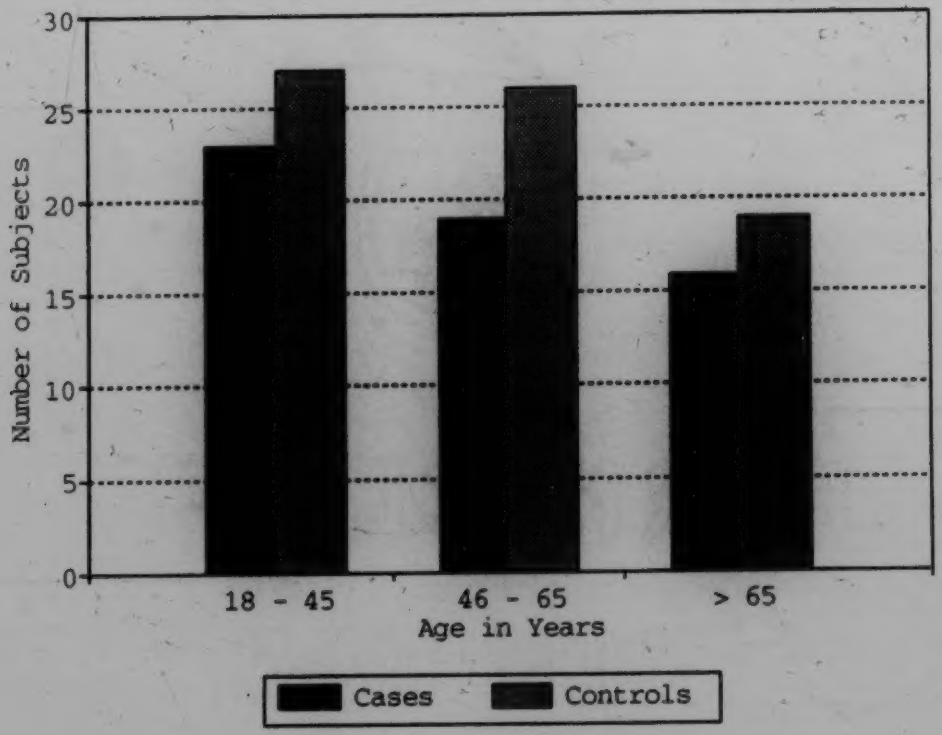


Figure 4.16. Subjects' gender in relation to the development of exit-site infections during the initial year following catheter insertion.

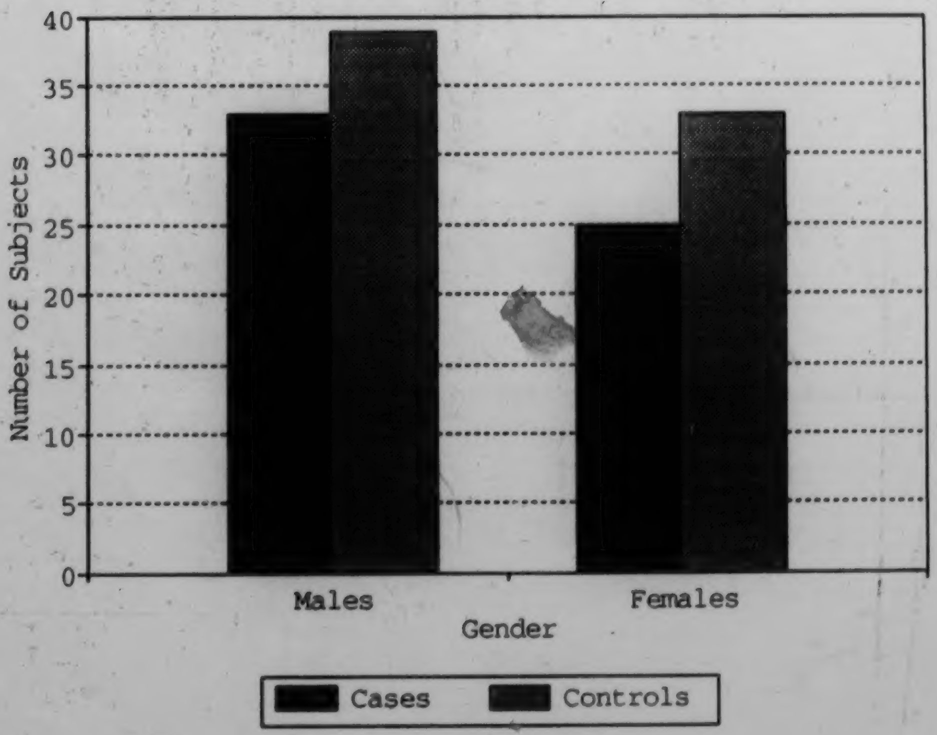


Figure 4.17. Subjects' vision in relation to the development of exit-site infections during the initial year following catheter insertion.

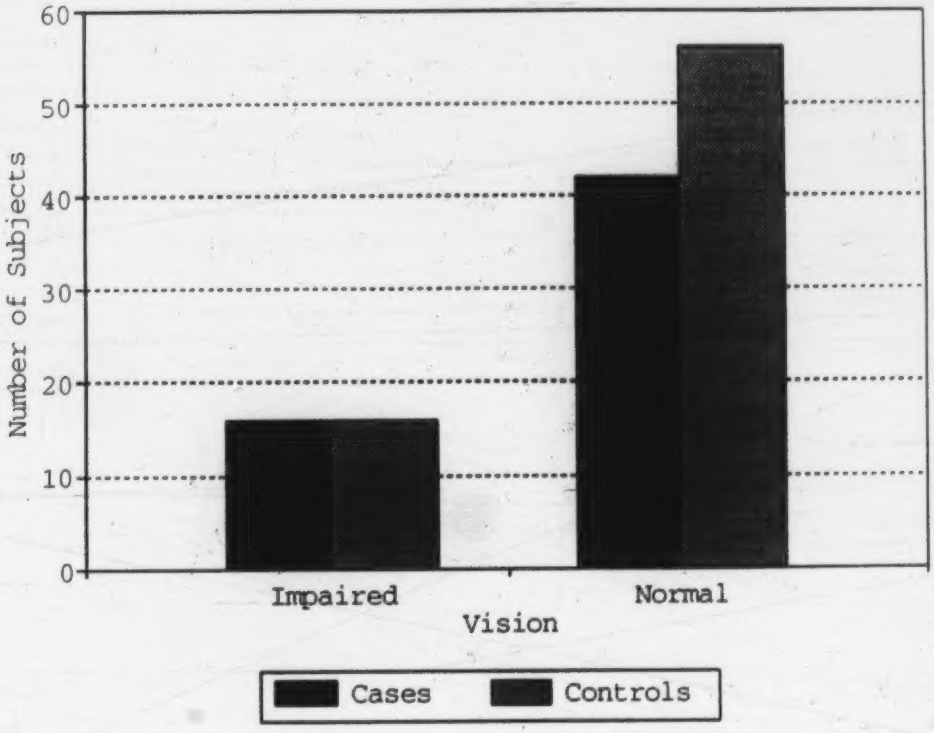
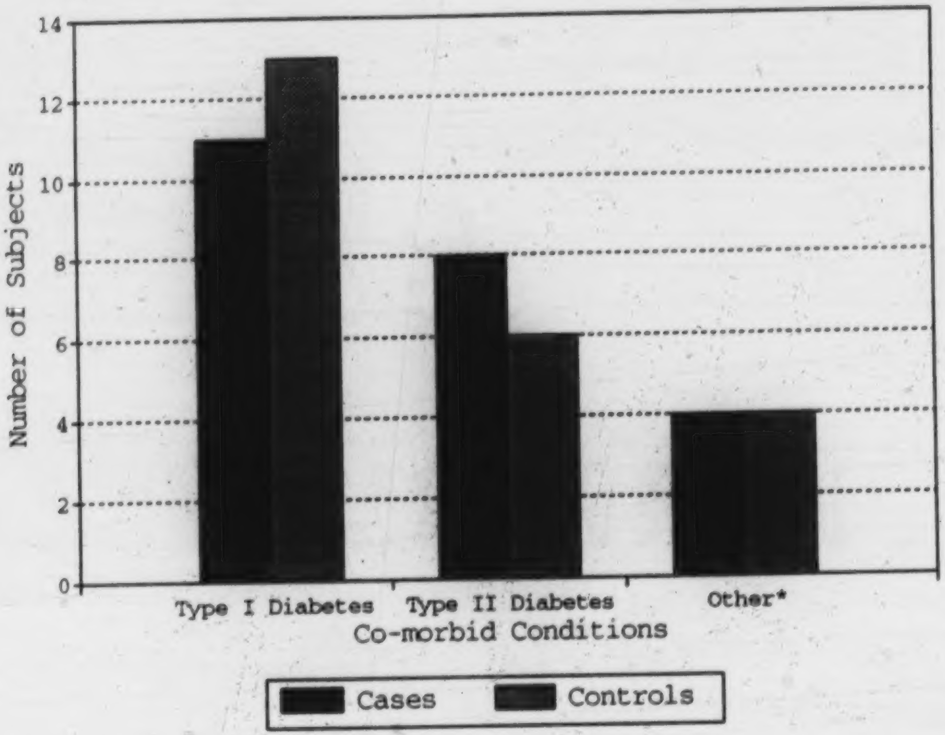


Figure 4.18. The presence co-morbid conditions in relation to the development of exit-site infections during the initial year following catheter insertion.



Note: * includes persons with rheumatoid arthritis, amyloidosis, scleroderma, and lupus erythematosis.

Catheter Insertion Factors

All catheters were surgically inserted and were of a straight Tenckhoff type design. One catheter had two cuffs, and the remainder were all single cuffed, with the cuff being placed in the deep fascia beneath the rectus muscle (see Table 4.10). Patients underwent a partial omentectomy at the time of catheter insertion whenever the omentum was visible and mobile. Direction of catheter tunnel was determined for 109 subjects. Of these, only two subjects appeared to have a catheter with a tunnel directed downward.

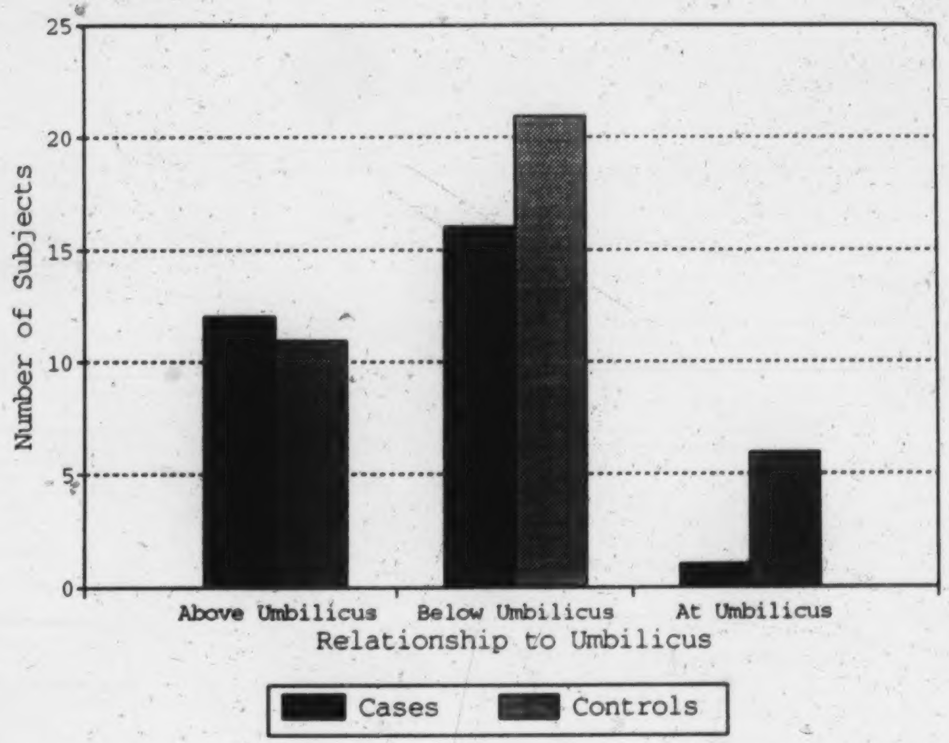
Location of the Exit-site on the Abdomen. In the partial sample where location on the abdomen could be determined, there was no significant difference in the incidence of exit-site infections [χ^2 (1, N = 128) = 0.89, p = 0.35, minimum expected frequency = 41.46]. Furthermore, the relationship of the catheter's exit-site to the umbilicus was not related to the development of exit-site infections [χ^2 (2, N = 67) = 3.14, p = 0.21, minimum expected frequency (EF) = 3.03, cells with EF < 5 = 2 (33.3%)] (see Figure 4.19).

Table 4.10.

Description of catheter insertion factors.

Factor	Characteristic	Frequency	% of sample
# of cuffs (n = 129)	one	128	98.46
	two	1	0.77
Direction of catheter tunnel (n = 109)	upward	107	82.30
	downward	2	1.50
Location of exit-site (n = 123)	right side	75	57.69
	left side	48	36.92
Relationship to the umbilicus (n = 67)	above	23	17.69
	below	37	28.46
	at umbilicus	7	5.39

Figure 4.19. The relationship of the exit-site to the subject's umbilicus in relation to the development of exit-site infections during the initial year following catheter insertion.



__Prophylactic Antibiotics__. Prophylactic antibiotics were used at the surgeon's discretion, and therefore, only 54 patients received antibiotics around the time of surgery. These antibiotics were administered pre-operatively, post-operatively, or during the surgery (see Figure 4.20). Twenty-five of the subjects (46.29%), who had received antibiotics around the time of surgery, were given antibiotics for co-existing medical problems (for example, reddened subclavian line sites, or for prophylactic coverage because of previous cardiac valve replacement).

Subjects who received antibiotics at the time of catheter insertion were not protected from developing an exit-site infection (see Table 4.11). The use of prophylactic antibiotics did not appear to be related to the development of exit-site infections [χ^2 (1, N = 130) = 0.001, p = 0.97, minimum expected frequency = 24.09]. Furthermore, the timing of antibiotic administration and the development of exit-site infections were not associated [χ^2 (2, N = 76) = 0.47, p = 0.79, minimum expected frequency = 2.67, cells with EF < 5 = 2 (33.3%)].

Figure 4.20. The timing of antibiotic administration in relation to the development of exit-site infections during the initial year following catheter insertion.

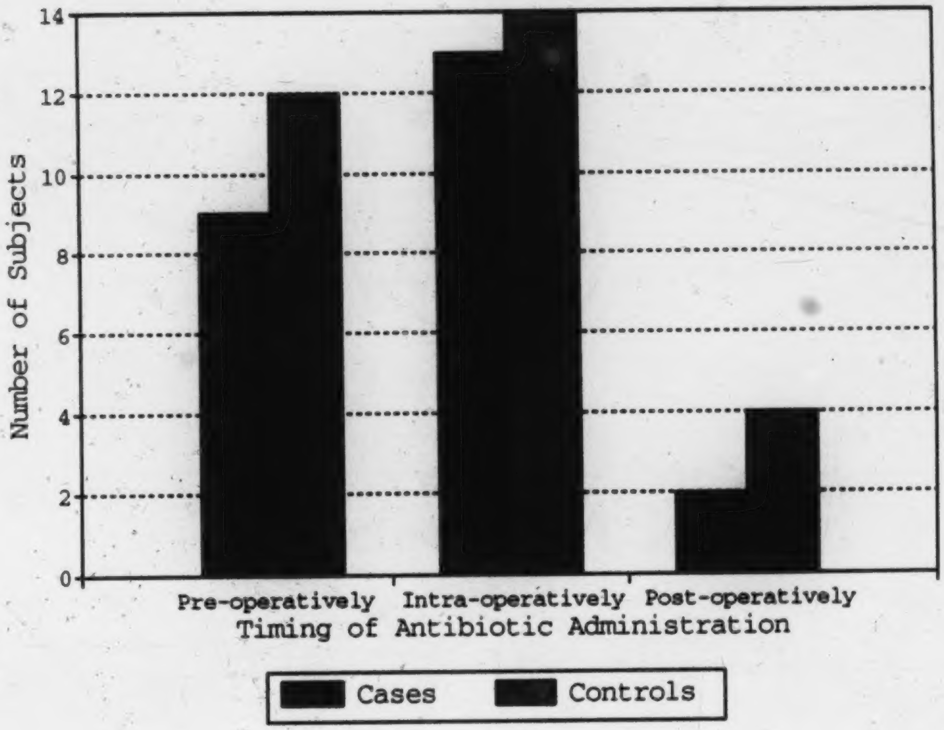


Table 4.11.

The administration of prophylactic antibiotics in relation to the development of exit-site infections during the initial year following catheter insertion.

Factor	Comparison	Odds ratio	Total # of subjects
Prophylactic Antibiotics	prescribed not prescribed	0.99	54 76
Antibiotic Timing	pre-operative intra-operative	0.80	21 27
	pre-operative post-operative	1.50	21 6
	intra-operative post-operative	1.86	27 6

Suture at the Exit-site. It was one surgeon's practice to insert a purse-string suture at the exit-site. Patients with a suture at the exit-site had a lower risk of infection than did those patients without a suture (see Table 4.12). The use of chi-square analysis suggested that the presence of a purse string suture at the exit-site was associated with a decreased number of exit-site infections developing during the initial year following catheter insertion [χ^2 (1, *N* = 130) = 4.24, *p* = 0.04, minimum expected frequency = 8.03].

Table 4.12.

The presence of a suture at the exit-site in relation to the development of exit-site infections.

Sample	Comparison	Odds ratio	Total # of subjects
Initial year	inserted	0.31	18
	not inserted		112
Initial six months	inserted	0.50	18
	not inserted		112
Latter six months	inserted	0.10	10
	not inserted		54

Further analysis of this variable (suture at the exit-site) within both partial time frames did not show a statistically significant association between the variable and the outcome (see Table 4.12). Chi-square analysis for the initial six month period following catheter insertion was not statistically significant [χ^2 (1, *N* = 130) = 1.42. *p* = 0.23, minimum expected frequency = 6.23]. However, chi-square analysis for the latter six month period of the initial year for this variable approached statistical significance [χ^2 (1, N =64) = 3.32, p = 0.07, minimum expected frequency EF = 2.19, cells with EF < 5 = 1 (25%)].

Procedural Factors

The remaining analyses considered miscellaneous factors that may be related to the development of exit-site infections. These factors included: the type of germicidal solution used for sterile dressing change procedures; the method used for healed exit-site care; and lastly, the length of time, post-operatively, before the person commenced peritoneal dialysis.

Germicidal Solution. No variation was found in the type of germicidal solution used for the performance of the sterile dressing change procedures, therefore no statistical analyses were performed. In all records where notations regarding supplies used for dressing changes were found, povidone-iodine was the solution used for cleansing the exit-site. In conjunction with the use of povidone-iodine, half-strength hydrogen peroxide was used to remove crusting prior to cleansing the exit-site.

Healed Exit-site Care. At the nurse's discretion, subjects were taught to change from using sterile dressing change procedures on the catheter's exit-site to healed exit-site care during a clinic visit. All patients were taught a standard method of caring for the healed exit-site. This method included the daily washing of the exit-site in the shower or bath with a surgical scrub solution, and then when dry, to wipe the exit-site with a povidone-iodine swab. Securing the catheter to the abdomen was suggested, while the wearing of a dressing over the catheter was at the individual's discretion.

It was not possible to ascertain from the medical records the extent to which subjects were compliant with the suggested healed exit-site care regimen. However, notations regarding the use of a dressing to cover the exit-site were found for 84 subjects. Of these, 53 persons (63.1%) used some form of dressing, typically gauze, to cover the healed exit-site.

Wearing a dressing over the healed exit-site decreased the risk (Odds ratio = 0.37) of an exit-site infection in the latter six months of the initial year following catheter insertion (see Table 4.13). However, this variable (use of dressing over healed exit-site) did not attain statistical significance in the use of chi-square analysis $[\chi^2 (1, N = 44) = 1.96$, $p = 0.16$, minimum expected frequency = 5.0].

Conversely, the risk of developing an exit-site infection during the initial six months following catheter insertion was increased (Odds ratio = 1.17), with the use of a dressing to cover a healed exit-site. Again the variable did not have a statistically significant association with the outcome $[\chi^2 (1, N = 84) = 0.11$, $p = 0.74$, minimum expected frequency = 10.70].

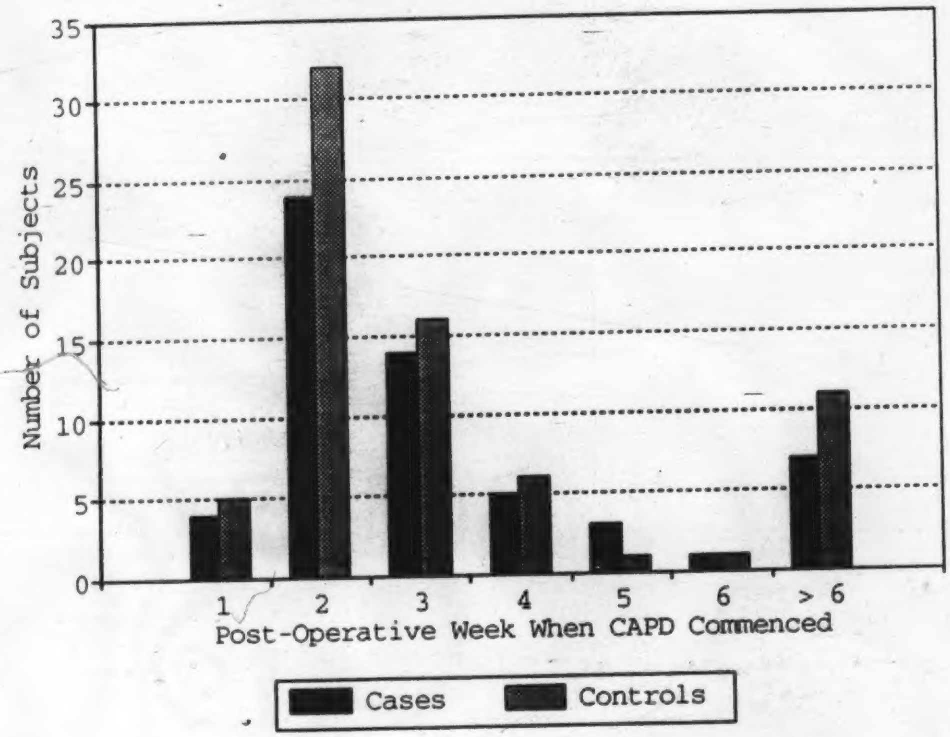
Table 4.13.

The use of a dressing to cover a healed exit-site in relation to the development of exit-site infections.

Sample	Comparison	Odds Ratio	Total # of subjects
Initial year	dressing	0.72	53
	no dressing		31
Initial six months	dressing	1.17	53
	no dressing		31
Latter six months	dressing	0.37	24
	no dressing		20

Commencement of Peritoneal Dialysis. Another variable that may be related to the development of exit-site infections is the length of time following catheter insertion prior to commencing peritoneal dialysis. Until the beginning of 1985, catheters were left without flushing for a period of ten days prior to the initiation of peritoneal dialysis. During 1985, a three to four day "flush" protocol was implemented. The protocol used to flush the catheters involved the intermittent instillation and prompt drainage of one litre of dialysate through the peritoneal catheter into the peritoneal cavity. The frequency of catheter flushes was ordered by the physician. However, a common practice was to flush the catheter four times during the first and second post-operative days, and then flushes were decreased to twice daily for the third and fourth day, or until the effluent did not appear blood stained. Following completion of the series of flushes, the catheter was capped and left unused until peritoneal dialysis was commenced. Five catheters were never used for peritoneal dialysis. For the remaining 125 patients, time from catheter insertion until CAPD commenced was between one and 276 days, with a mean length of time of 22.55 days

Figure 4.21. The length of time post-operatively that the person commenced peritoneal dialysis in relation to the development of exit-site infections during the initial year following catheter insertion.



(standard deviation of 30.0). With the exclusion of two outliers (dialysis commencement at 167 and 276 days), the mean decreased to 19.35, (SD = 14.72).

The variable, number of days from catheter insertion until CAPD commenced was collapsed into seven groups. These groups were based upon the number of weeks from surgery until the person commenced peritoneal dialysis (see Figure 4.21). This variable did not have a statistically significant association with the development of exit-site infections [χ^2 (6, N = 130) = 1.88, $p = 0.93$, minimum expected frequency (EF) = 0.89, cells with EF < 5 = 7 (50%)].

Modelling the Incidence of Exit-Site Infection

Two logistic regression equations were computed following the identification of statistically significant associations between the independent and the dependent variables of interest. The first equation considered the effect of independent variables on the development of exit-site infections during the year following catheter insertion. The effect of the independent variables on the development of exit-site infections within six months of catheter insertion was the focus of the second logistic regression equation.

Initial Year Following Catheter Insertion

Using chi-square analysis, one independent variable was identified as having a statistically significant association with the development of exit-site infections in the year following catheter insertion. This variable, the insertion of a purse string suture at the exit-site was associated with a decreased incidence of exit-site infections in those patients having the suture. The use of logistic regression analysis also indicated that this variable (the presence of a suture at the exit-site) was a significant predictor of exit-site infection [F = 3.85, df(1,127), p = 0.05] in this group of CAPD patients.

Initial Six Months Following Catheter Insertion

Frequency of sterile dressings performed during the first post-operative week and the time that the patient and/or family member commenced the performance of the sterile dressings post-operatively, were identified as being significantly associated with the development of exit-site infections within six months of catheter insertion through the use of chi-square analysis. These two variables, frequency of dressing changes during week one [F = 1.42, df(8, 112), p =

0.20] and the time post-surgery that the person and/or family member commenced the performance of the sterile dressing [*F* = 0.54, *df*(1,87), *p* = 0.46] were not significant predictors of exit-site infection.

Summary

The research findings were presented in relation to the research questions. Using chi-square analyses, it was found that three independent variables were associated with the development of exit-site infections during the two time periods. These variables were: the use of a purse string suture at the exit-site with the development of exit-site infections during the initial year following catheter insertion; the frequency of sterile dressings performed during the first post-operative week, and the length of time post-operatively that the patient and/or family commenced the performance of the sterile dressing and the development of infections during the first six months following catheter insertion. In the logistic regression analyses, only the presence of a suture at the exit-site was found to be a statistically significant predictor of exit-site infection.

V. DISCUSSION AND CONCLUSIONS

The purposes of this chapter are to discuss the findings and present the conclusions of the research. Results of the analysis will be summarized and discussed in relation to the literature. Following a general discussion of the research findings, the limitations of the study will be addressed. Suggestions for further research and implications for nursing practice and administration conclude the chapter.

This research study examined the association between initial post-operative nursing care received by a person following peritoneal dialysis catheter insertion and the later development of exit-site infections. Data were collected retrospectively, using a case-control study design. The final sample consisted of 130 subjects, 56 of whom (44.4%) had an exit-site infection within one year of catheter insertion.

The use of odds ratio calculations and chi-square analyses suggested that the placement of a suture at the exit-site decreased the incidence of exit-site infections during the initial year following catheter insertion. In addition, these statistical models suggested that the frequency of sterile dressings performed on the catheter during the first post-operative week and the length of time following catheter insertion that the patient and/or family member commenced the performance of the sterile dressings was associated with the development of exit-site infections within six months of catheter insertion. Using logistic regression analysis, only the presence of a suture at the exit-site was a statistically significant predictor of exit-site infection.

Discussion of Findings

Incidence of Exit-site Infection

The incidence of exit-site infections at one year was 44.8%, despite the use of a more restrictive definition of exit-site infection than is normally found within the literature. The incidence of exit-site infections at one year following catheter insertion ranges in the literature from 22 to 46% (Abraham et al., 1988; Lindbald et al., 1989; Luzar & Lewis, 1989). The definition used in this study was restrictive in that a diagnosis of exit-site infection was dependent upon the presence of redness at the exit-site with or without exudate, in conjunction with antibiotic administration. This definition differs from that of previous researchers who consider that redness and/or exudate alone signify an exit-site infection (Abraham et al., 1988; Cantaluppi et al., 1985; Holley et al., 1990; Khanna & Twardowski, 1988; Luzar et al., 1990; Pegues et al., 1989; Piraino, 1989; Waraday et al., 1987). However, the additional criteria of antibiotic administration was deemed necessary to complete the definition within the context of a retrospective chart review. Furthermore, antibiotic usage differentiates infection from inflammation in clinical practice.

Frequency of Sterile Dressings

Recommendations regarding the frequency of post-operative dressing changes on the peritoneal dialysis catheter suggest that dressing changes should be performed infrequently to prevent unnecessary catheter movement within the exit-site wound (Khanna & Twardowski, 1988; 1989; Oreopoulos et al., 1987). Two research studies support this practice (Jensen et al., 1989; Roldaan et al., 1990). The current study through the use of chi-square analysis, suggests that the frequency of sterile dressings may be associated with the early (within six months of catheter insertion) development of exit-site infections. However, this association was not maintained when the data was analyzed using logistic regression. It should be noted that less variability than expected was found in the frequency of sterile dressing changes performed on the catheter during the initial post-operative week, particularly at the low end of the scale. Only 12 subjects (9.2%) had the sterile dressing change performed three or four times that initial week. The majority (90.8%), of the subjects had the dressing change performed on their catheter five or more times during the initial post-operative week. The discrepancy between the results of the chi-square and that of the logistic regression can be explained by the limited variability of the variable. Because there were only a few subjects whose frequency of sterile dressings being performed at the lower and upper range of the scale, the chi-square analysis used a large proportion of cells with expected frequencies of less than five (10, 55.6%). The use of these cells with low expected frequencies resulted in an inflated chi-square result.

The frequency of sterile dressings performed on the subjects during the initial post-operative period in the current study was high, ranging on average from five to seven sterile dressing changes performed on the catheter during each post-operative week. Therefore, subjects were exposed to an almost daily manipulation of the catheter. This practice is not consistent with recommendations regarding initial post-operative catheter care (Khanna & Twardowski, 1988; Oreopoulos et al., 1987).

Contributing to the frequency of sterile dressings was the observation that 65 subjects (50% of the sample) had their initial post-operative dressing change performed on the day of surgery. The dressing was changed by the nurses on the patient's return from the operating room whenever the dressing appeared untidy or the titanium connector was visible. This variable, time until initial post-operative dressing change is performed was not significantly associated with the development of exit-site infections. The findings are somewhat disconcerting given that recommendations in the literature suggest that the initial post-operative dressing remain undisturbed for a week to prevent torque movements of the catheter in the exit-site (Khanna & Twardowski, 1988). However, it may be that this variable also lacked sufficient variability to adequately address the question.

Duration of Sterile Dressing Changes

Research literature is not available regarding the ideal duration of time that sterile dressings should be used to cover the catheter. In the current study, sterile dressings were used to cover the catheter's exit-site from three until greater than seven weeks following catheter insertion. It was not possible to determine from the review of the subjects' medical records, or from discussions with the nursing staff what criteria were used to assess the extent of wound healing around the catheter, or to determine the appropriate time to stop the use of sterile dressings. The teaching of healed exit-site care appeared to occur when convenient, at a routine clinic visit. Although this variable was not significantly associated with the development of exit-site infection in this study, the extended use of sterile dressings has implications for nursing practice that will be discussed later.

Personnel Performing the Sterile Dressing Change

It has been recommended that sterile dressing changes to the peritoneal dialysis catheter be performed only by specially trained registered nurses (Clayton, 1981; Copely, 1987; Copely et al., 1988; Fuchs et al., 1990; Khanna & Twardowski, 1989; Piraino, 1989). In the current study, sterile dressings were changed by the home dialysis nursing staff, the ward nursing staff, and later by the patient and/or a family member.

The practice of having patients and/or family members performing the sterile dressings on the peritoneal dialysis catheter was associated (though not significantly) with a decreased exit-site infection rate. The infection rate was lower when patients and/or family members assumed the performance of the sterile dressings at some point in the initial post-operative period. Despite the lack of statistical significance, the results suggest that limiting the dressing change procedure to a single person, or to a group of persons with a vested interest in the success of the peritoneal dialysis catheter, may be of benefit in the reduction of exit-site infections.

The association between the time post-operatively that the person and/or family members commences the performance of the sterile dressings and the development of exit-site infections within six months of catheter insertion, supports the practice of teaching patients and/or family members to perform sterile dressing changes during the initial post-operative period. However, this association identified through the use of chi-square analysis was not supported in the logistic regression analysis. Again, the reason for this discrepancy was the large (6, 50%) proportion of cells in the chi-square analysis that used an expected frequency of less than five, resulting in an inflated chi-square result.

In the current study, in addition to patients and family members, both home dialysis and ward nurses performed the sterile dressing changes in the post-operative period. Each group of nurses brings different experience and training in the CAPD procedures to their work. A possible variation in knowledge, skill, ability and interest in the care of the person with a peritoneal dialysis catheter by each group of nurses, may have influenced the results. This variation in the type of nursing personnel who performed the sterile dressing procedure, limits generalizations that can be drawn from the research.

Catheter Insertion Factors

The type and method of insertion of peritoneal dialysis catheters has been shown by researchers to influence the development of exit-site infections (Copely, 1987). In the current study, all the catheters, with the exception of one, were of a single cuff, straight Tenckhoff type design. In addition, only two catheters were inserted in a manner that the tunnel was directed downward. The lack of variation in the method of surgical insertion served to control for any effect that catheter type and insertion variations may have on the development of exit-site infections.

The relationship of the catheter to the umbilicus could not be determined for 63 subjects (48.5%). In the study, relationship of the exit-site to the umbilicus did not appear to be associated with development of exit-site infections. However, these findings are limited because knowledge of the catheter exit-site in relation to the subject's belt line (not just the umbilicus) was not possible from a review of medical records.

It has been suggested that the use of prophylactic antibiotics at the time of catheter insertion may influence the development of exit-site infections (Copely, 1987; Copely et al., 1988; Khanna & Twardowski, 1988; Oreopoulous et al., 1987; Piraino, 1989). However, similar to results reported by others, antibiotic use at the time of surgery did not influence the development of exit-site infections (Dimitriadis et al., 1987; Nolen et al., 1988). Limitations to these results pertaining to antibiotic use, include that the antibiotics were given at various times and through a variety of routes, and in 25 patients the antibiotics were prescribed for a purpose other than prophylactic coverage during surgical insertion of a foreign body.

Use of a suture at the catheter's exit-site is not recommended, since the presence of the suture material may act as an additional foreign body in the wound and thus may encourage bacterial colonization (Oreopoulous et al., 1987). However, the presence of a purse-string suture at the exit-site in 18 of the subjects was significantly associated a decreased incidence of exit-site infections amongst that portion of the sample. These results should be treated cautiously since the proportion of the sample having sutures was small. In addition, the use of a suture was limited to one surgeon and the suture was purse-string in nature. It should be noted that the suture material did not enter the exit-site itself, but rather, served to anchor the catheter to the abdominal wall and thus prevented movement of the catheter within the exit-site.

Patient Characteristics

Factors related to the patients themselves, such as advanced age, visual impairment, or diabetes did not appear to be associated with the development of exit-site infections. Conflicting reports can be found regarding the influence of co-morbid conditions, such as diabetes, on development of exit-site and tunnel infections (Bernardini et al., 1988; Gibel, Quintana, Tzamaloukas, & Garcia, 1989; Vogt et al., 1987). One group of researchers (Suzuki et al., 1989) have suggested that in exit-site locations that are easily visible by the person, the incidence of exit-site infections is decreased. However, the direct influence that visual impairment may have on the development of exit-site infections has not been the subject of a systematic investigation.

Procedural Factors

In addition to the factors discussed previously, a group of factors related to the CAPD procedures were examined. Clinical research studies have been carried out by nurses and others in relationship to the best method to care for the healed exit-site (Clayton et al., 1981; Fuchs et al., 1990; Luzar et al., 1990; Moore, 1989; Prowant et al., 1988; Starzomski, 1984). The current study included as a variable, the wearing of a dressing on the healed exit-site and the possible influence that this practice may have on the development of exit-site infections. The practice of wearing a dressing over the healed exit-site was associated (although not significantly) with a decreased incidence of infection within the latter six months of the initial year following catheter insertion. However, subjects who wore a dressing on a healed exit-site had an increased risk of developing an exit-site infection during the initial six months following catheter insertion. These results suggest that the use of dressings on healed exit-sites in relation to the development of exit-site infections warrants further study. The findings of the current study in relation to the use of a dressing on a healed exit-site are limited since the recording of the manner of healed exit-site care and the subjects' compliance with the regimen was frequently not available in the medical records. Furthermore, data regarding the subject's use of a dressing on the healed exit-site were available for only 84 subjects, only 64.6% of the sample.

The timing of the initiation of peritoneal dialysis was considered. However, this variable was not associated with the development of exit-site infections. Subjects who were started on CAPD procedures in the early post-operative period did not seem to be at greater risk for developing an exit-site infection than were those patients who commenced dialysis later following insertion, or not at all.

Limitations of the Study

This section will address the limitations of the study. Initially, methodological problems including sample size, the extent of missing data and the reliability and validity of data will be addressed. Then limitations related to the design will be outlined.

Sample size was adequate at 130 persons, and by limiting the use of logistic regression analysis to those variables that had been found to be significantly associated with the development of exit-site infections through the use of chi-square analyses, the statistical power was estimated at 0.97. Therefore, the risk of making a type two statistical error was small, assuming a moderate effect size (Cohen, 1977). However, although the majority of chi-square analyses had adequate statistical power, a number of equations extended to nine degrees of freedom. In addition, there were chi-square equations that used a large percentage of cells with small (less than 5) expected frequencies. A larger sample would have increased the statistical power of the chi-square analyses and increased the size of the expected frequencies within the cells.

The incidence of exit-site infections within the sample was high, particularly at six months following catheter insertion (33.8%). Although it appeared from the chi-square analysis that the frequency of dressing changes performed during the initial post-operative week was related to the development of exit-site infections within this time frame, these results were not maintained with the use of logistic regression analysis. Had a larger sample size been obtained and with a greater variability, some variables currently not associated with the development of exit-site infections may have attained statistical significance. However, a larger sample size was not possible in the current study because the sampling method used all possible subjects within the sampling time frame. The sample only excluded those persons who were not adults, those persons who were cared for post-operatively in another hospital (thereby introducing extraneous variables), and those persons who had their peritoneal dialysis catheter removed prior to six months of treatment without an exit-site infection. Extension of the time limits was not possible since prior to 1985 (with the introduction of a form specific to the character of the exit-site), data regarding exit-site care and infections were not available on the medical record.

In the study there were extensive missing data. One variable in particular, the relationship of the catheter to the person's umbilicus, was missing for 48.4% of the sample. Therefore, the power of the statistical analysis for this variable is decreased.

In addition, data were missing from the questions of interest, the frequency of dressing changes during the individual weeks post-operatively for 14.6% of the sample during the third post-operative week, and rising to 48.5% during the fifth post-operative week. Patients and/or family members began to do the dressing changes at home, and frequency of dressing changes was not recorded. Therefore, the possible influence that the frequency of dressing changes during the latter post-operative weeks in relation to the development of exit-site infections could not be fully considered.

For a third variable, the influence of healed exit-site care methods, data were missing for 35.4% of the sample. In addition, information available on the medical records regarding the use of dressing worn on healed exit-site was incomplete. Determinations were made dependent upon random notations in the patient's chart regarding the use of dressings. Therefore, it was not known if the practice of using a dressing was continual or only sporadic.

A major limitation related to the use of medical records for data collection relates to the reliability and validity of the information obtained from the medical records. Data were collected retrospectively, therefore, validation of the information recorded on the medical record with another source was not possible. For example, it is possible that the data underrepresented the frequency of dressing changes and that dressings were performed that were not recorded in the patients record. These omissions could influence the accuracy of the research findings.

Selection bias was not of concern in the data collection. Patients were considered cases whenever notations of redness, with or without exudate was present on the medical record in conjunction with a prescription for antibiotic use. However, the use of a more liberal definition of exit-site infection was not appropriate since the researcher had no way to determine the reliability of the diagnosis of presence of redness at the exit-site. The use of the criteria of antibiotic administration validated the clinical impression that an exit-site infection existed. The antibiotics were administered to treat what the physician thought to be an exit-site infection. The use of this definition may have contributed to an underrepresentation of exit-site infections since not all infections were diagnosed by the physician as requiring antibiotics. Infections may have resolved with the use of conservative measures such as increased exit-site care and the use of an absorbent dressing.

Implications of the Study

There are a number of implications for nursing practice, administration, and research that arise from the study. Each area of nursing will be considered and discussed in relation to the possible implications identified from the research findings.

Nursing Practice and Administration

This study identifies implications for nursing practice and administration. Currently, nurses are responsible for changing sterile dressings on the peritoneal dialysis catheter during the initial post-operative period. The decision to change a surgical dressing remains at the discretion of the individual nurses. The frequency of sterile dressings changed on the individual weeks in the initial post-operative period is high and nurses did not appear to have an adequate rationale for changing dressings identified in the chart. Most remarks preceding the dressing change procedure was that the dressing was dry and intact. If this was the case, the question "Why was the dressing changed?" needs to be considered. Did the nurse caring for the patient believe that it was in the patient's best interest to change the dressing? Or was the dressing changed because of the routines of the unit, or preferences of the nurse(s)?

Performing a sterile dressing procedure on a peritoneal catheter is costly in terms of nursing time and supplies. The indications for performing sterile dressings must be considered in the development of protocols for the care of the peritoneal catheter. Supplies for performing a sterile dressing procedure cost significantly more than those supplies necessary for care of the healed exit-site. Therefore, sterile dressings being performed by nurses and/or patients at home after the usual time frame for the use of sterile dressings is indicated greatly increases the costs associated with CAPD treatment programs.

The observation that 65 patients had their initial post-operative dressing changed on the day of surgery raises questions regarding the beliefs that nurses hold regarding the purpose of a sterile dressing. Do nurses believe that sterile dressings cover the catheter to protect the catheter, or to make the incision more acceptable to the patient? Should the former be true, then changing the catheter dressing on the day of surgery would be inconsistent with their perceptions of any protective function that the sterile dressing may provide. Furthermore, if the dressing is changed simply because it is untidy, communication between the surgical staff and the ward nursing staff may be lacking in regards to what constitutes an acceptable peritoneal dialysis catheter dressing.

Nurses frequently noted that a "comfort" dressing was applied to the catheter. This statement supports the premise that nurses believed that the purpose of the dressing was to provide the patient with comfort, that is, to make the catheter exit-site more acceptable to the patient. The use of the term "comfort dressing" may also influence the value that the patient places on the dressing, and as such, influence the patient's compliance with a dressing change regimen. Defining what is meant by nurses in their use of the term "comfort dressing" will assist in identifying the values that nurses place upon the use of sterile dressings.

Nursing Research

From this study, a number of aspects of peritoneal dialysis catheter care that require further research have been identified. The questions of interest in this study, the frequency and duration of sterile dressings used to cover a peritoneal dialysis catheter, need to be considered in a prospective randomized trial of catheter care protocols. The current study did not support the hypothesis that the frequency of sterile dressings performed on the catheter during the initial post-operative period may influence the development of exit-site infections. However, these results require replication.

Future research into the care of the peritoneal dialysis catheter during the initial post-operative period requires identification and control of extraneous variables that may have an influence on the development of exit-site infection. In addition to the variables included in the current study, additional variables such as the identification and/or treatment of Staphylococcal nasal carriers may affect the development of both post-operative and later exit-site infections (Ahrens et al., 1987; Luzar et al., 1989; Piraino, 1990; Zimmerman et al., 1988). Furthermore, the use of a formal grading system for the characteristics of exit-site healing, such as the one suggested by Twardowski (1990), could be utilized to document the healing of catheter's exit-site and assist in the determination of when healed exit-site care should be commenced. Research using Twardowski's classification would also serve to validate the categories and thus strengthen the classification system.

In addition, a standardized definition of what constitutes an exit-site infection needs to be developed. Currently, in the literature, the operational definition of an peritoneal dialysis catheter exit-site infection differs for each group of researchers. This practice makes it difficult to accurately compare, contrast, and generalize the research findings. Therefore, it is important to the care of the person with a peritoneal dialysis catheter that an universally accepted definition of exit-site infection be developed.

Conclusions

This research project was a case-controlled study of therapy efficacy designed to consider the association between the initial post-operative nursing care of the person with a peritoneal dialysis catheter and the development of peritoneal dialysis catheter exit-site infections. The incidence of infections in the sample was 44.8% at one year following catheter insertion. Odds ratio, chi-square, and logistic regression analyses suggested that the presence of a suture decreased the incidence of exit-site infection during the initial year following catheter insertion. From the chi-square analyses, it appeared that the frequency of sterile dressing changes performed on the catheter during the first post-operative week and the length of time following catheter insertion that the patient and/or family member commenced the performance of the sterile dressing were associated with the development of exit-site infections within six months of catheter insertion. Because of the low expected frequencies within cells, statistical significance of these variables with the outcome was not attained when logistic regression analysis was used. In addition, the research design allowed limited control of confounding variables (for example, method of healed exit-site care) and there was a substantial amount of missing data.

In conclusion, the results of this research project did not suggest a relationship between post-operative nursing care of the person with a peritoneal dialysis catheter and the development of exit-site infections associated with the catheter. However, the generalizability of these findings is limited because of the retrospective nature of the study, the missing data, and the lack of variability on some variables. A larger sample size would increase the likelihood of detecting small effects. Further research is necessary to develop an understanding of the possible role that the initial post-operative nursing care may have in the prevention of exit-site infections associated with peritoneal dialysis catheters.

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Appendix A

INSTRUMENT

Data Collection Form # 1

Demographic Information

1. Age in years: ____________

2. Gender: ____________
   Male (1) Female (2)

Related Medical Information

1. Cause of renal failure: ____________
   Unknown (1) Hypertension (2) Diabetes (3)
   Glomerulonephritis (4) Polycystic Disease (5)
   Other Cystic Disorders (6) Renal Cancer (7)
   Cancer - other than renal (8) Amyloidosis (9)
   Other Disease (10)

2. Visual impairment: ____________
   None (1)
   Visual impairment noted on medical record (2)

3. Presence of co-morbid conditions: ____________
   Yes (1) No (2)

   Insulin dependent diabetes: ____________
   Yes (1) No (2)

   Non-insulin dependent diabetes: ____________
   Yes (1) No (2)

   Parkinsonism: ____________
   Yes (1) No (2)

   Rheumatoid Arthritis: ____________
   Yes (1) No (2)

   Other: ____________________

Data Collection Form # 2

Prior End-Stage Renal Disease Treatment

1. Treatment modality prior to catheter insertion: ___
Conservative therapy (1)
Preparatory hemodialysis (2) Hemodialysis (3)
Transplant (4)

2. Total duration of renal replacement therapy (Hemodialysis/Transplant) prior to CAPD in years: ___
less than 1 (1) 1 to 5 (2) 6 to 10 (3)
11 to 15 (4) greater than 15 (5)

Catheter Related Information

1. Date of insertion _____/_____/_____/

2. Length of time from catheter insertion until CAPD commenced in days: ___________

3. Type of catheter: ___________
Tenckhoff (1) TWH 2 / OZ (2) Gortex (3)
Lifecath (4) Other (5)

4. Number of cuffs: ___________
One (1) Two (2) Unknown (3)

5. Direction of catheter tunnel: ___________
Upwards (1) Downwards (2) Unknown (3)

6. Location of catheter on abdomen: ___________
Right side (1) Left side (2) Unknown (3)

7. Relationship of catheter to umbilicus: ___________
Above (1) Below (2)
At umbilicus/belt line (3) Unknown (4)

8. Suture at the exit-site: ___________
No (0) Yes (1)

9. Prophylactic Antibiotics: ___________
No (1) Yes (1)

10. Timing of Antibiotics if given: ___________
Pre-operatively (1) Post-operatively (2)
Intra-operatively (3)

Data Collection Form # 3

Exit-Site Infection Information

1. Date of documented exit-site infection: ___/___/___

2. Length of time from insertion of catheter until exit-site infection: __________ (in months)

3. Description of site: erythema __________
Yes (1) No (2)

purulent drainage __________
Yes (1) No (2) Unknown (3)

visible cuff erosion _______
Yes (1) No (2) Unknown (3)

4. Adminstration of antibiotics: __________
yes (1) No (2)

5. Concurrent peritonitis: ______________
Yes (1) No (2)

6. Outcome of catheter: ___________
Exit-site infection resolved (1)
Catheter removed due to recurrent exit-site infection (2)
Catheter removed due to peritonitis (3)
Catheter removed for other reason (4)

7. Outcome of treatment: ____________
New peritoneal catheter (1)
Transfer to hemodialysis (2)

Data Collection Form # 4

Initial Post-Operative Care of the Catheter

1. Duration of sterile dressing changes post-operatively (time post catheter insertion until the person commences healed exit-site care: ______________

    1 week (1)   2 weeks (2)   3 weeks (3)
    4 weeks (4)   5 weeks (5)   6 weeks (6)
    7 weeks (7)   greater than 7 weeks (8)

2. Number of dressing changes per week: in times per week

    week one __________   week two __________
    week three __________   week four __________
    week five __________   week six __________
    week seven __________

3. Patient taught to do self-dressing changes: _______
    Yes (1) No (2) Unknown (3)

4. Relative (or other non-nurse) taught to do dressing changes: __________
    Yes (1) No (2) Unknown (3)

5. Time from insertion of catheter until patient and/or relative commenced doing dressing changes in days: __________

6. Germicidal solution used for dressing change: _____
    Povidone-iodine (1)
    Half strength hydrogen peroxide (2)   Savlon (3)
    Other (4)

Data Collection Form #5

Healed Exit-Site Care

1. Type of healed exit-site care: ____________
   Shower procedure (1) Other (2)
   Unknown (3)

2. Use of povidone-iodine: __________
   Yes (1) No (2) Unknown (3)

3. Use of dressing: __________
   Yes (1) No (2) Unknown (3)

4. Type of dressing if used: ____________
   Gauze (1) Airstrip (2) Op-site (3)
   Other (4) No dressing (5)